Submitter : Leslie Lloyd **Date:** 01/03/2006

Organization : AOTA

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1502-FC-61-Attach-1.DOC

CMS-1502-FC-61-Attach-2.DOC

AOTA The American Occupational Therapy Association, Inc.

Occupational Therapy: Skills for the Job of Living

Via email to www.cms.hhs.gov/regulations/ecomments

January 3, 2006

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1502-FC
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, District of Columbia 21244-1850

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Final rule with comment

Dear Doctor McClellan:

The American Occupational Therapy Association (AOTA) represents more than 35,000 occupational therapy professionals, many of whom provide outpatient services to Medicare beneficiaries. We appreciate the opportunity to comment on the Medicare Part B payment policies applicable for calendar year 2006. This final rule with comment was published in the *Federal Register* on November 21, 2005 (70 Fed. Reg. 70116). AOTA's detailed comments follow.

I. Therapy Cap

AOTA is concerned that the approach outlined in the Final Rule towards developing alternatives to the outpatient therapy caps is not fully reflective of what Congress mandated. In the Final Rule, the Centers for Medicare and Medicaid Services (CMS) articulates that it has made significant progress towards, "*establishing a payment policy 'based on the classification of individuals' as required by the Congress in the BBA section 4541(d)(2) and again in the BBRA section 221(c)(2)(b).*" 70 Fed. Reg. at 70266 (emphasis added). However, this is taken out of context. The BBA does not require CMS to establish a payment policy based on the classification of individuals. Rather, the BBA required CMS to report on "*recommendations on the establishment of a revised coverage policy of outpatient physical therapy services and outpatient occupational therapy services.* It appears from the statutory language that in the BBA Congress did not intend for CMS to establish a new payment policy, but rather to merely study the possibilities and report back to Congress on its findings and recommendations.

BBRA makes similar requests and further expands the content of the requests. The BBRA required CMS to study therapy and to make recommendations on two items: a mechanism for assuring appropriate utilization of outpatient therapy services, and an alternative payment policy. The statutory language in BBRA directs CMS "*to submit to Congress a report that includes recommendations on (A) the establishment of a mechanism for assuring appropriate utilization of outpatient [rehabilitation therapy] services...and (B) the establishment of an alternative payment policy for such services based on classification of individuals by diagnostic category.*

The American Occupational Therapy Association, Inc. 4720 Montgomery Lane Bethesda, MD 20814-3425 301-652-2682 301-652-7711 Fax 800-377-8555 TDD www.aota.org

functional status, prior use of services (in both inpatient and outpatient settings), and such other criteria as the Secretary determines appropriate.... The recommendations shall include how such a mechanism or policy might be implemented in a budget-neutral manner." (emphasis added). Again, Congress did not direct CMS to establish a new payment policy without its approval; rather it requires CMS to merely make recommendations on establishing a new payment policy for outpatient therapy services. **AOTA is concerned that CMS' efforts to establish a new payment policy exceed its Congressional mandate to study the matter.**

Furthermore, Congress clearly directed CMS to make recommendations on mechanism to assure appropriate utilization of outpatient therapy services, but not to implement such mechanisms. **AOTA suggests that CMS' impending application of the medically unbelievable edits (MUE) established by its Correct Coding Initiative (CCI) contractor, Reliance Safeguard Solutions, is inconsistent with Congress' desire to legislate a mechanism for assuring appropriate utilization of services. The implementation of any policy which arbitrarily limits specific interventions would adversely affect CMS' ability to collect valid data on "appropriate utilization."**

Finally, the BBA directs CMS to make recommendations based on classifying beneficiaries by diagnostic category and prior use of services. The BBRA takes this requirement a step further and directs CMS to make recommendations based on classifying beneficiaries by these two criteria plus functional status. However, in the Final Rule, CMS states that it is working on classifying beneficiaries by ICD-9 diagnosis codes. The Final Rule itself identifies the limitations of classifying beneficiaries based upon diagnostic codes and that measurements of the severity and acuity of a patient's condition is neither available through the current claim form and are not consistently gathered or reported by therapists. **AOTA encourages CMS to focus on determining the appropriate mechanism for gathering accurate information about a beneficiary's functional status throughout the course of the therapy and to also look at the prior use of therapy services across all settings. Due to the breadth of such a study, AOTA suggests that CMS first gather this data by studying a subset of beneficiaries, namely those outpatient therapy users who are in the top 5% for utilization. AOTA encourages CMS to conduct these studies with as much clinical feedback as possible from the professional associations.**

The AOTA requests that due consideration be given to these comments. Thank you, again, for the opportunity to comment on this Final Rule. We look forward to a continuing dialogue with CMS on these issues as they apply to occupational therapy.

Sincerely,

Leslie Stein Lloyd, Esq.
Director, Reimbursement and Regulatory Policy

AOTA The American Occupational Therapy Association, Inc.

Occupational Therapy: Skills for the Job of Living

Via email to www.cms.hhs.gov/regulations/ecomments

January 3, 2006

Mark McClellan, M.D., Administrator
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Department of Health and Human Services
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The AOTA requests that due consideration be given to these comments. Thank you, again, for the opportunity to comment on this Final Rule. We look forward to a continuing dialogue with CMS on these issues as they apply to occupational therapy.

Sincerely,

Leslie Stein Lloyd, Esq.
Director, Reimbursement and Regulatory Policy

Submitter : **Dr. Mark McClellan** **Date: 01/03/2006**

Organization : **American College of Radiology**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1502-FC-62-Attach-1.PDF

ACR™
AMERICAN COLLEGE OF
RADIOLOGY

January 3, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC and CMS-1325-F
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Final Rule

Dear Dr. McClellan:

The American College of Radiology (ACR), representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, submits comments on the following areas of the "Revisions to Payment Policies Under the Physician Fee Schedule" published in the Federal Register on November 21, 2005.

Please see below for our comments on 1) Multiple Procedure Reduction; 2) Nuclear Medicine Services; 3) Implementation of Practice Expense; 4) Malpractice RVUs; 5) Miscellaneous Practice Expense; 6) New Codes in 2006; and 7) NCS Timeframes.

Multiple Procedure Reduction

The ACR appreciates CMS's decision to not implement the 50 percent reduction on multiple procedures done on contiguous body areas in the same session for 2006. However, the ACR is disappointed and concerned with CMS's decision to implement a 25 percent reduction in 2006 and phase-in of a 50 percent reduction in 2007. The ACR agrees that there are some efficiencies in clinical labor activity when certain combinations of multiple imaging procedures are performed in the same session. However, we do not agree that these efficiencies are uniform across all families and we do not believe the data supports either the 25 or 50 percent reductions. **The ACR strongly believes that implementation of any multiple procedure reduction should have been delayed at least one year to allow further analysis to determine the appropriate "multiple procedure families" and percent reduction.** The ACR looks forward to beginning a working process with CMS in January 2006 to determine the appropriate percent reduction for imaging procedures in each of the families.

Same Session Versus Separate Sessions

The ACR appreciates CMS's clarification in the definition of "same session". In this final rule, CMS clarified that a single session is "when more than one of the imaging service in a single family is provided to the patient during one encounter and therefore, the subsequent procedure would be subjected to the multiple payment reduction rule. However, if the patient has a separate encounter on the same day for a medically necessary reason and receives a second imaging service from the same family, CMS considers this as a separate session and the multiple payment reduction does not apply. For the latter, CMS established that physicians use modifier -59 to indicate "separate sessions." There is limited familiarity with the proper use of modifier -59 among physicians at large. As such, **the ACR remains concerned that physician payment will be unfairly discounted when no economies have occurred and therefore, requests that this process be closely monitored and that CMS provide ACR with quarterly analysis of the frequency of claim submissions for "same session" as well as "separate sessions".**

Nuclear Medicine Services

The ACR applauds CMS's decision to incorporate diagnostic and therapeutic nuclear medicine services into the definition of "radiology and certain other imaging services", which are already subject to physician self-referral prohibition. The ACR further supports CMS's decision to delay the effective date of this new policy until January 1, 2007 and not "grandfather" existing arrangements.

Practice Expense

Supplemental Survey

The ACR is very disappointed and remains concerned that CMS decided to not utilize the supplemental survey data, which it had previously accepted, for radiology practice expense values for 2006. The ACR followed strict guidelines outlined by CMS and used an approved contractor submitting that data in the time frame defined by CMS. The ACR also invested significant financial resources, staff time and physician volunteer time to complete the survey.

Specialties that conducted the supplemental survey and submitted data, which was ultimately accepted as valid by CMS, should not be penalized for their efforts. CMS specifically requested all specialties to conduct a supplemental survey and extended the deadline to ensure that as much data was submitted as possible. The ACR complied with CMS's request. By initially proposing a change from top-down to bottom-up methodology, CMS effectively precluded the opportunity for public comment on the supplemental surveys. By the subsequent complete reversal of its initial proposal, CMS has created a technicality by which it can now defend exclusion of this rigorously acquired data from direct practice expense values in 2006.

While the ACR appreciates CMS's initial willingness to work with specialties to determine how to handle the practice expense data collected through the supplemental survey, it does not appreciate the regulatory gridlock into which this process has fallen. **The ACR therefore strongly encourages CMS to reconsider using the radiology supplemental data for the 2006 practice expense values.** The ACR is available to discuss this further and looks forward to working closely with CMS to have its data incorporated into the Medicare Physician Fee Schedule (MFS).

Multi-specialty Survey

According to this final rule, CMS is exploring the idea of conducting a multi-specialty indirect practice expense survey. The ACR appreciates CMS's efforts to ensure that the practice expense methodology treats all specialties equitably. Going forward, a multi-specialty survey may be an option to capture the general change in cost of delivering medical services across all specialties however the survey performed by the ACR should not be supplanted by other data without thorough review. In the meantime, **the ACR recommends CMS use the accepted supplemental survey data from specialties that invested time and resources to provide CMS with accurate specialty practice expense data.**

Malpractice RVUs

In this final rule, CMS decided to exclude data for all specialties that perform less than 5 percent of a particular service from the malpractice calculation. The ACR is concerned that this 5 percent threshold will inappropriately remove some specialties performing radiology codes, especially interventional radiology services, in the calculation of malpractice RVUs. **The ACR recommends that CMS reconsider its decision and continue to calculate the malpractice RVUs based on the 1 percent threshold.**

New Codes in 2006 (Intracranial Codes)

In this final rule, CMS assigned a status indicator of N for intracranial codes 61630, 61635, 61640, 61641, and 61642 on the basis that these codes are noncovered under Medicare due to a National Coverage Decision. The ACR is concerned with CMS's decision to not accept the RUC approved work values for these codes. These are critical procedures performed when no other viable treatments are available. Since these codes were valued by the RUC, **the ACR recommends that CMS reconsider its decision and publish the values in the MFS.** CMS has set precedence by publishing RVUs for other procedures for which it does not cover in the RBRVS. Private insurers can use the published values as a reference for payment of these services.

Neurointerventional techniques such as angioplasty and stenting provide additional therapeutic options for patients with cerebrovascular atherosclerosis and vasospasm and in some circumstances have become the standard of care. **The ACR requests that CMS reconsider its decision to not cover these life-saving procedures under Medicare.**

Miscellaneous Practice Expense

PET and PET/CT Codes

The ACR appreciates CMS reassigning the indirect practice expense values to PET and PET/CT codes 78811, 78812, 78813, 78814, 78815, 78816, 78491, 78492, 78459, 78608, and 78609 on the professional component side. However, the technical component remains carrier priced for these codes. **The ACR seeks explanation as to why the RUC approved inputs have not been translated into RVUs similar to all other new RUC approved codes and why the technical component for these codes, especially for codes 78811 to 78816, new codes effective January 1, 2005, have been assigned to be carrier priced.**

Imaging Rooms

The ACR would like to thank CMS for accepting ACR's recommendation on various imaging rooms. The ACR appreciates CMS's willingness to work with the College to ensure appropriate cost and equipment items for these rooms.

Practice Expense for Codes 36475 and 36476

In this final rule, the ACR agrees with CMS's decision to add the tilt table for codes 36475 and 36476. However, since a tilt table is necessary for both methods of endovenous ablation and their respective primary and add-on codes, the ACR recommends that CMS add the tilt table to codes 36478 and 36479 as well. However, the ACR does not support the additional 15 minutes clinical labor time being added to these codes as the description of physician work for the endovenous ablation codes describes the patient being placed in the Trendelenberg position, when needed, by the physician.

Price for Film Alternator

CMS has $27,500 listed for the cost of a film alternator in their database. The ACR would like to verify this with the manufacturer and submit the appropriate price to CMS staff in the near future.

NCD Timeframes

CMS proposed to implement a 30-day comment period and eliminate the reference to the 90-day implementation for the national coverage process time-line. The ACR supports CMS's decision to adopt this proposal.

Conclusion

Thank you for the opportunity to comment on this final rule. While recent legislative action has created even more uncertainty and instability for the technical component reimbursement of

imaging services, the ACR hopes that the Agency will continue to embrace its philosophy of working with physicians and their professional societies in order to create a stable and equitable resource-based payment system.

We anticipate that the Practice Expense Advisory Committee (PEAC) approved direct practice expense data as well as the indirect practice expense data derived from our CMS and The Lewin Group approved supplemental survey will have significant value and weight as the future Technical Component (TC) payments in the Physician Fee Schedule are developed. These data represent the best and most accurate cost data available to the Agency and should not be discarded.

The ACR looks forward to continued dialogues with CMS officials about these and other issues affecting radiology and radiation oncology. If you have any questions or comments on this letter or any other issues with respect to radiology and radiation oncology, please contact Angela Choe at 800-227-5463 ext. 4556 or via email at achoe@acr.org.

Respectfully Submitted,

Harvey L. Neiman, MD

Harvey L. Neiman, MD, FACR
Executive Director

cc: Herb Kuhn, CMS
Ken Simon, MD, CMS
Carolyn Mullen, CMS
Pamela West, CMS
Rich Ensor, CMS
Ken Marsalek, CMS
John A. Patti, MD, FACR, Chair, ACR Commission on Economics
Bibb Allen, Jr., MD, FACR, Vice-Chair, ACR Commission on Economics
Pamela J. Kassing, ACR
Maurine Spillman-Dennis, ACR
Angela J. Choe, ACR

Submitter : Dr. Joseph Corriere **Date:** 01/03/2006

Organization : American Urological Association

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1502-FC-63-Attach-1.DOC

American
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January 3, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Re: CMS-1502-FC – Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; and CMS-1325-F – Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under part B; Final Rule

Dear Dr. McClellan:

On behalf of the American Urological Association (AUA), representing 10,000 practicing urologists in the United States, we are pleased to submit comments on the final rule for the 2006 physician fee schedule and for the Competitive Acquisition Program (CAP). Our comments address the current status of the methodology used to calculate practice expense relative value units, in-office RVUs for CPT code 52648 and the application of least costly alternative (LCA) policies to the CAP.

RESOURCE-BASED PRACTICE EXPENSE RVUS

The AUA is extremely disappointed that CMS did not use our supplemental practice expense (PE) survey data to update the 2006 PE relative value units (RVUs) for *all* procedures performed by urologists. We appreciate that CMS followed our request to use AUA survey data to update PE RVUs for urology drug administration procedures, as this will assure that the benefits of the budget neutrality exemption from the 2003 Medicare Modernization Act (MMA) are fully realized. However, CMS did not comply with the full requirements of the MMA, which mandated use of our data to update PE RVUs for *all* urology procedures.

AUA
Atlanta, Georgia
May 20–25, 2006

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Furthermore, although CMS indicated in the rule that the urology drug administration PE RVUs were updated using the AUA's supplemental survey data, we are disappointed that Addendum B did not reflect the updated calculations. We understand that this was an unintended error and that CMS is in the process of preparing a correction notice with updated PE RVUs for urology drug administration procedures. **We urge CMS to publish the correction notice as soon as possible and, if necessary due to timing of the correction notice, to make any PE RVU changes for urology drug administration codes retroactive to January 1, 2006.**

Also, we strongly object to the reasoning that CMS withdrew its practice expense proposals in the final rule in part due to a calculation error that caused almost all the PE RVUs published in the August 8, 2005 proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology. However, this error should have been handled through the use of a correction notice as occurred with other errors in the proposed rule rather than withdrawing the proposals, as now urologists are paying for CMS's error through the loss of practice expense payments rightfully due them.

Based on CMS's regulations regarding the Criteria for Submitting Supplemental Practice Expense Survey Data and the MMA language, the AUA dedicated considerable time and significant financial resources to conduct and submit a practice expense supplemental survey. We exercised this option under the good faith assumption that if our survey met the criteria established by CMS, the data would be used to adjust our practice expense data so that it would more accurately reflect the true costs of urology services provided in 2006 and beyond. This assumption was reasonable, since CMS has previously accepted and implemented supplemental survey data from other medical societies.

CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. **The AUA will participate in these meetings and provide input; nevertheless, it is unfair and inequitable that implementation of our survey data has been delayed and that we are forced to go through an entirely different process than groups who had supplemental survey data accepted prior to 2006. In fact, CMS updated the practice expense RVUs for *all* fee schedule services provided by oncologists in the January 7, 2004 final rule using language from section 303(a)(1) of the MMA, but subsequently interpreted this same language for urology to include *only* drug administration services.**

IN-OFFICE PRACTICE EXPENSE RVUS FOR CPT CODE 52648

Currently, there are two CPT codes that describe laser therapies used to treat benign prostatic hyperplasia (BPH):

CPT code 52647 – *Non-contact laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)*

CPT code 52648 - *Contact laser vaporization with or without transurethral resection of*

prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)

At the recommendation of the AUA, CPT code 52647 has had Medicare non-facility practice expense (PE) relative value units (RVUs) since 2001. Conversely, CPT code 52648 does not currently have non-facility PE RVUs, because at the time it was reviewed by the PEAC, the AUA felt that it was inappropriate to assign non-facility PE RVUs for a procedure requiring general anesthesia. However, it has come to our attention that some accredited, well-equipped urology offices around the country are performing CPT code 52648. Because we do not wish to penalize urologists who are performing this procedure in offices that are properly equipped to handle general anesthesia, we are conducting a review of this issue.

We indicated in our proposed rule comments that the AUA's review process fell outside of the comment period for the 2006 fee schedule and that we did not want this timing issue to preclude urologists from receiving appropriate payment for performing CPT code 52648 in their offices in 2006.

Therefore, we requested that CMS, on an interim basis, assign 2006 non-facility payment for CPT code 52648 based on a crosswalk of practice expense direct cost inputs from CPT code 52647. We further indicated that after the AUA review process is complete, we expect that direct cost inputs for CPT code 52648 will then be forwarded through the proper process for review and approval, allowing the assignment of permanent non-facility inputs for 52648.

Because CMS did not address this request in the final rule, we urge CMS to include this in a fee schedule correction notice as soon as possible so that urologists performing this procedure in the office in 2006 can be appropriately reimbursed.

COMPETITIVE ACQUISITION PROGRAM

In the July 6, 2005 CAP interim final rule with comment, CMS specifically solicited comments on how to deal with this issue of carrier LCA policies in later stages of implementing the CAP program. CMS is dealing with it initially by excluding leuprolide from the CAP in 2006. To date, Medicare carriers have implemented LCA policies for Leuprolide acetate (J9217) and Goserelin acetate (J9202) in most (but not all) states based on the belief that the two drugs are equally efficacious. This means that carriers will only pay for the cheaper drug, Goserelin Acetate, even when physicians bill for Leuprolide Acetate.

CMS acknowledged that the existence of LCA policies, and the fact that they will apply under the CAP just as they apply outside the CAP, have obvious implications for the provision of certain drugs under the CAP. Because Leuprolide is subject to LCA policies in all carrier jurisdictions (but not all states), its inclusion in the current CAP drug category would have the effect of requiring vendors to supply the drug at the cost of goserelin in each instance in which a participating CAP physician orders it, regardless of the price established for leuprolide under the bidding and single price determination processes and regardless of the geographic location of the participating CAP physician.

The AUA responded to this request for comment by saying that CMS should either notify carriers to discontinue LCA policies and if not to at the very least carve out of the CAP all drugs to which LCA policies apply. However, in the final rule, CMS says "after considering the comments, we continue to believe that the decisions outlined in the July 6, 2005 interim final rule with comment pertaining to which drugs are included in the CAP drug category maintain a balance between physician access to LHRH analogues and vendor risk associated with the application of LCAs for these drugs" (70 *Fed. Reg.* at 70243-44).

The AUA continues to disagree with CMS's decision in this regard, as this issue will undoubtedly become an administrative burden and a problem for CMS, its carriers, the designated carrier, CAP vendors and CAP physicians due to the other LHRH analogues that are still included in the CAP in 2006. More and more carriers are now applying LCA policies beyond J9202 and J9217 to the other drugs within the class of luteinizing hormone-releasing hormone or LH/RH drugs. **We don't understand why CMS is carving out J9217 from the CAP due to concern about CAP vendors taking losses if a physician ordered J9217 but the CAP vendor could only be paid for J9202 (currently the least expensive LHRH drug), but that CMS does not seem concerned that CAP vendors will take losses if physicians order any of the other LHRH drugs as well.** The current LH/RH drugs included in the CAP are:

	Drug	Name	Units
J3315	Triptorelin Pamoate	Trelstar	3.75 mg
J9202	Goserelin acetate implant	Zoladex	3.6 mg
J9219	Leuprolide acetate implant	Viadur	65 mg
J9225	Histrelin Implant	Vantas	50 mg

Thank you for considering our comments. If you have any questions or need additional information, please contact Robin Hudson, AUA Manager of Regulatory Affairs, at 410-689-3762 or rhudson@auanet.org.

Sincerely,

Joseph N. Corriere, Jr., M.D.
President

James B. Regan, M.D.
Chair, Health Policy Council

American
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January 3, 2006

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P.O. Box 8017
Baltimore, MD 21244-8017

Re: CMS-1502-FC – Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; and CMS-1325-F – Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under part B; Final Rule

Dear Dr. McClellan:

On behalf of the American Urological Association (AUA), representing 10,000 practicing urologists in the United States, we are pleased to submit comments on the final rule for the 2006 physician fee schedule and for the Competitive Acquisition Program (CAP). Our comments address the current status of the methodology used to calculate practice expense relative value units, in-office RVUs for CPT code 52648 and the application of least costly alternative (LCA) policies to the CAP.

RESOURCE-BASED PRACTICE EXPENSE RVUS

The AUA is extremely disappointed that CMS did not use our supplemental practice expense (PE) survey data to update the 2006 PE relative value units (RVUs) for *all* procedures performed by urologists. We appreciate that CMS followed our request to use AUA survey data to update PE RVUs for urology drug administration procedures, as this will assure that the benefits of the budget neutrality exemption from the 2003 Medicare Modernization Act (MMA) are fully realized. However, CMS did not comply with the full requirements of the MMA, which mandated use of our data to update PE RVUs for *all* urology procedures.

AUA
Atlanta, Georgia
May 20–25, 2006

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Furthermore, although CMS indicated in the rule that the urology drug administration PE RVUs were updated using the AUA's supplemental survey data, we are disappointed that Addendum B did not reflect the updated calculations. We understand that this was an unintended error and that CMS is in the process of preparing a correction notice with updated PE RVUs for urology drug administration procedures. **We urge CMS to publish the correction notice as soon as possible and, if necessary due to timing of the correction notice, to make any PE RVU changes for urology drug administration codes retroactive to January 1, 2006.**

Also, we strongly object to the reasoning that CMS withdrew its practice expense proposals in the final rule in part due to a calculation error that caused almost all the PE RVUs published in the August 8, 2005 proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology. However, this error should have been handled through the use of a correction notice as occurred with other errors in the proposed rule rather than withdrawing the proposals, as now urologists are paying for CMS's error through the loss of practice expense payments rightfully due them.

Based on CMS's regulations regarding the Criteria for Submitting Supplemental Practice Expense Survey Data and the MMA language, the AUA dedicated considerable time and significant financial resources to conduct and submit a practice expense supplemental survey. We exercised this option under the good faith assumption that if our survey met the criteria established by CMS, the data would be used to adjust our practice expense data so that it would more accurately reflect the true costs of urology services provided in 2006 and beyond. This assumption was reasonable, since CMS has previously accepted and implemented supplemental survey data from other medical societies.

CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. **The AUA will participate in these meetings and provide input; nevertheless, it is unfair and inequitable that implementation of our survey data has been delayed and that we are forced to go through an entirely different process than groups who had supplemental survey data accepted prior to 2006. In fact, CMS updated the practice expense RVUs for *all* fee schedule services provided by oncologists in the January 7, 2004 final rule using language from section 303(a)(1) of the MMA, but subsequently interpreted this same language for urology to include *only* drug administration services.**

IN-OFFICE PRACTICE EXPENSE RVUS FOR CPT CODE 52648

Currently, there are two CPT codes that describe laser therapies used to treat benign prostatic hyperplasia (BPH):

CPT code 52647 – *Non-contact laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)*

CPT code 52648 - *Contact laser vaporization with or without transurethral resection of*

prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)

At the recommendation of the AUA, CPT code 52647 has had Medicare non-facility practice expense (PE) relative value units (RVUs) since 2001. Conversely, CPT code 52648 does not currently have non-facility PE RVUs, because at the time it was reviewed by the PEAC, the AUA felt that it was inappropriate to assign non-facility PE RVUs for a procedure requiring general anesthesia. However, it has come to our attention that some accredited, well-equipped urology offices around the country are performing CPT code 52648. Because we do not wish to penalize urologists who are performing this procedure in offices that are properly equipped to handle general anesthesia, we are conducting a review of this issue.

We indicated in our proposed rule comments that the AUA's review process fell outside of the comment period for the 2006 fee schedule and that we did not want this timing issue to preclude urologists from receiving appropriate payment for performing CPT code 52648 in their offices in 2006.

Therefore, we requested that CMS, on an interim basis, assign 2006 non-facility payment for CPT code 52648 based on a crosswalk of practice expense direct cost inputs from CPT code 52647. We further indicated that after the AUA review process is complete, we expect that direct cost inputs for CPT code 52648 will then be forwarded through the proper process for review and approval, allowing the assignment of permanent non-facility inputs for 52648.

Because CMS did not address this request in the final rule, we urge CMS to include this in a fee schedule correction notice as soon as possible so that urologists performing this procedure in the office in 2006 can be appropriately reimbursed.

COMPETITIVE ACQUISITION PROGRAM

In the July 6, 2005 CAP interim final rule with comment, CMS specifically solicited comments on how to deal with this issue of carrier LCA policies in later stages of implementing the CAP program. CMS is dealing with it initially by excluding leuprolide from the CAP in 2006. To date, Medicare carriers have implemented LCA policies for Leuprolide acetate (J9217) and Goserelin acetate (J9202) in most (but not all) states based on the belief that the two drugs are equally efficacious. This means that carriers will only pay for the cheaper drug, Goserelin Acetate, even when physicians bill for Leuprolide Acetate.

CMS acknowledged that the existence of LCA policies, and the fact that they will apply under the CAP just as they apply outside the CAP, have obvious implications for the provision of certain drugs under the CAP. Because Leuprolide is subject to LCA policies in all carrier jurisdictions (but not all states), its inclusion in the current CAP drug category would have the effect of requiring vendors to supply the drug at the cost of goserelin in each instance in which a participating CAP physician orders it, regardless of the price established for leuprolide under the bidding and single price determination processes and regardless of the geographic location of the participating CAP physician.

The AUA responded to this request for comment by saying that CMS should either notify carriers to discontinue LCA policies and if not to at the very least carve out of the CAP all drugs to which LCA policies apply. However, in the final rule, CMS says "after considering the comments, we continue to believe that the decisions outlined in the July 6, 2005 interim final rule with comment pertaining to which drugs are included in the CAP drug category maintain a balance between physician access to LHRH analogues and vendor risk associated with the application of LCAs for these drugs" (70 *Fed. Reg.* at 70243-44).

The AUA continues to disagree with CMS's decision in this regard, as this issue will undoubtedly become an administrative burden and a problem for CMS, its carriers, the designated carrier, CAP vendors and CAP physicians due to the other LHRH analogues that are still included in the CAP in 2006. More and more carriers are now applying LCA policies beyond J9202 and J9217 to the other drugs within the class of luteinizing hormone-releasing hormone or LH/RH drugs. **We don't understand why CMS is carving out J9217 from the CAP due to concern about CAP vendors taking losses if a physician ordered J9217 but the CAP vendor could only be paid for J9202 (currently the least expensive LHRH drug), but that CMS does not seem concerned that CAP vendors will take losses if physicians order any of the other LHRH drugs as well.** The current LH/RH drugs included in the CAP are:

	Drug	Name	Units
J3315	Triptorelin Pamoate	Trelstar	3.75 mg
J9202	Goserelin acetate implant	Zoladex	3.6 mg
J9219	Leuprolide acetate implant	Viadur	65 mg
J9225	Histrelin Implant	Vantas	50 mg

Thank you for considering our comments. If you have any questions or need additional information, please contact Robin Hudson, AUA Manager of Regulatory Affairs, at 410-689-3762 or rhudson@auanet.org.

Sincerely,

Joseph N. Corriere, Jr., M.D.
President

James B. Regan, M.D.
Chair, Health Policy Council

Submitter : Mr. Craig A. Choate **Date:** 01/03/2006

Organization : intraFUSION

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1502-FC-64-Attach-1.PDF

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Urological
Association

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www.UrologyHealth.org
www.urologichistory.museum

January 3, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Re: CMS-1502-FC – Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; and CMS-1325-F – Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under part B; Final Rule

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Sincerely,

Joseph N. Corriere, Jr., M.D.
President

James B. Regan, M.D.
Chair, Health Policy Council

Submitter : Dr. Mary Hager **Date:** 01/03/2006

Organization : The American Dietetic Association

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1502-FC-65-Attach-1.DOC

American Dietetic Association
Your link to nutrition and health.[sm]

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1120 Connecticut Avenue, Suite 480
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202/775-8277 FAX 202/775-8284

January 3, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
7500 Security Lane
Baltimore, MD 21244-8017

RE: 42 CFR Parts 405, 410, 411, 413, 414, 424, 426 [CMS-1502-FC].
Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006.

Dear Dr. McClellan:

The American Dietetic Association (ADA) appreciates this opportunity to re-affirm our comments on the Notice of Final Rule for the CY 2006 Physician Payment Schedule published November 21, 2005 (70 FR 70116) . We urge you to consider this information as you refine the Final Rule for CY 2006 and initiate procedures to revise methodology for relative values for the following year's rule.

The ADA represents nearly 65,000 food and nutrition professionals working to improve the nutritional status of Americans. As primary prevention, strong evidence indicates that nutrition helps promote health and functionality and affects each individual's quality of life. As secondary and tertiary prevention, medical nutrition therapy (MNT) is a cost-effective disease management strategy that lessens chronic disease risk, and which slows disease progression and reduces symptoms. Medicare Part B covers MNT provided by registered dietitians (RDs) for diabetes and chronic renal disease.

Telehealth for Individual MNT

ADA supports the final rule decisions to add individual MNT to the Medicare list of services that can be provided via telehealth, and recognize registered dietitians (RDs) and nutrition professionals as qualified healthcare professionals who can submit claims for individual MNT provided via telehealth. ADA welcomes the opportunity to assist CMS in educating Medicare RD providers on telehealth services and to inform and encourage physician practitioners and beneficiaries of this new service delivery option.

PE Methodology and Elimination of the Non-Physician Work Pool
ADA agrees with CMS' decision to withdraw the entire PE methodology proposal and to refine the process for the CY 2007 proposed rule.

We ask to participate in the process as a full partner when CMS considers how to revise the methodology to calculate CPT code relative values. When CMS convenes a meeting with interested medical societies to discuss the direct and indirect PE methodology and elimination of the non-physician work pool, as well as meet individually with groups to discuss their particular concerns, ADA representatives need to cover our unique experience and knowledge along with the other interested medical societies. We also request to meet separately with CMS to discuss the medical nutrition therapy CPT code RVUs, including the direct and indirect PE inputs for the codes.

The current methodology and the proposed bottom-up methodology for MNT services fail to appropriately recognize RD work. With the proposed CY 2006 RVUs for MNT CPT codes, the agency once again has overlooked the intent of Congress regarding the implementation (and payment) for medical nutrition therapy services. In particular:

- *MNT code PE inputs are not valid.*
  RD work should be fully recognized and accounted for in the code RVUs.
  The current direct inputs do not accurately reflect the RD's full clinical labor and professional service that is required to provide MNT. The inputs fail to represent the RD's pre-, intra-, and post-work times to provide this service as the current values significantly underestimate, or omit certain pre- and post-service activities.

  ADA recommends PE time be allocated consistently within the three MNT codes for pre-services, such as reviewing medical records and laboratory data, equipment set-up, and other clinical activities (greeting the patient, treatment room set-up); and for post-services such as dismantling and storing equipment and educational materials such as food models; documentation and conducting follow-up communications with the referring physicians, patients and family members as appropriate and necessary. CMS has not accurately represented these activities in the direct input data used to calculate the MNT RVUs.

  PE data that ADA discussed with the AMA PEAC in February 2005 indicates that the following minutes of clinical labor are accurate:

  - 39 minutes total clinical labor time, including RD professional work for 97802 and 97803 per unit code;
  - 28 minutes total clinical labor time, including RD professional work for 97804 per unit code.

  These work data are significantly different from the arbitrary direct input values that CMS has used in the proposed PE calculation of RVU for the MNT codes -- 25 minutes 97802; 22 minutes for 97803, and 9 minutes for 97804. (See accompanying table).

- *The RVUs for initial MNT (97802) and follow-up MNT (97803) should be the same.*
  Since the MNT codes are time-based, the complexity and amount of time spent completing the pre-, intra-, and post-service times will be reflected in the number of

units used for each code. Therefore, the four-minute difference that the agency currently used in the direct PE values for determining the total RVUs is not appropriate. Both initial and follow-up MNT for individual encounters should have the same direct PE RVUs.

- *CMS should pay RDs and qualified nutrition professionals 100% of the MNT code RVUs or pay 85 percent of designated physician codes.*
  While current policy is inconsistent with the authorizing statute, it also lacks intellectual integrity. In the agency's determination that there is no physician work for MNT services, and its policy to take 85 percent of the physician fee schedule values for the MNT CPT codes, the agency has created an unfair payment anomaly towards registered dietitians and nutrition professionals who provide and bill for the services using the MNT CPT codes. If the agency continues to support the premise that there is no physician work for the MNT codes, this 'double discount' can be corrected by paying RDs 100% of the physician fee schedule.

  Alternatively, there is external support for a far more transparent approach to MNT RVUs. AMA indicates in the CPT 2005 publication, "for medical nutrition therapy assessments and/or intervention performed by a physician, see Evaluation and Management or Preventive Medicine service codes." If CMS believes the MNT statute for payment must be followed, then the agency should base the RD payment rate on 85% of the total physician RVUs for these codes (eg. E&M code 99203). CMS has established a precedent of paying a percentage of the physician fee schedule for codes used by other non-physician practitioners. For example, social workers, certified nurse midwives, physician assistants, and certified nurse specialists are paid a percentage of the physician's fee schedule when providing services that otherwise would have been performed by the physician. The payment amount is based on the physician code to provide the service, not other non-physician practitioner codes for the service.

- *CMS should establish work RVUs for MNT codes provided by RDs.*
  ADA asks the agency to work with our professional association to determine appropriate values and methodology that accurately reflects the professional work of RDs for MNT services.

  If a work RVU cannot be established, ADA asks CMS to consider establishing a new PE category that specifically references the professional's work effort. This would be a separate calculation to the current PE that accounts for clinical labor to support the RD in providing MNT services.

Physician Liability Insurance (PLI) Calculation for RDs

ADA agrees with CMS and the PLI workgroup's decision that nonphysician professionals, such as RDs, incur PLI costs similar to the lowest cost physician specialty; the lowest current risk factor of 1.0. While ADA realizes that CMS was unable to identify all Medicare providers in the proposed and final rule, we note that reference to liability insurance for registered dietitians continues to be omitted in the agencies' comments.

Recognition of RD Medicare Providers by CMS

In closing, in future Federal Register notices and general communications that relate to Medicare Part B providers, ADA urges the agency to include registered dietitians in the printed list of Medicare Part B providers. RDs were omitted in all tables included in CMS-1502-P and CMS-1502-FC, in the list of providers eligible to "opt-out" of Medicare, and other references to

Medicare Part B providers in the proposed rules for the CY 2006 physician fee schedule (70 FR 45764).

ADA looks forward to partnering with CMS in the development of the RVUs for CY 2007 final rule and education on new changes for the 2006 calendar year. Please do not hesitate to call Mary Hager, PhD, RD, Senior Manager, Regulatory Affairs, (202) 775-8277, ext. 1007 or Pam Michael, Director of Nutrition Services Coverage Team, 312-899-4747, with any questions or requests for additional information.

Best regards,

Pam Michael, MBA, RD
Director of Quality, Outcomes and Coverage

Mary H. Hager, PhD, RD
Senior Manager, Regulatory Affairs

CMS PE inputs

2006 NPRM labor cost inputs (excerpt)

HCPCS	Source	CPEP	Staff Type	Description	Rate	Pre-Time NF	Intra-Time NF	Post-Time NF	Pre-Time F	Intra-Time F	Post-Time F	Valued NF	Valued F
97802	HCPAC	RUC	L043B	Registered Dietician	0.43	3	15	7	0	0	0	Y	Y
97803	HCPAC	RUC	L043B	Registered Dietician	0.43	3	15	4	0	0	0	Y	Y
97804	HCPAC	RUC	L043B	Registered Dietician	0.43	1	7	1	0	0	0	Y	Y

Source: 42 CFR Parts 405, 410, 411, 413, 414, 426 [CMS-1502-P].
Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006- Proposed Rule

Submitter : **Brian McGinty** **Date: 01/03/2006**

Organization : **Biogen Idec**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1502-FC-66-Attach-1.DOC

biogen idec™

December 30, 2005

VIA HAND DELIVERY

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 443-G, Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1502-FC and CMS-1325-F (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B)

Dear Administrator McClellan:

Biogen Idec appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) final rule refining implementation of portions of the Medicare Modernization, Prescription Drug and Improvement Act of 2003 (MMA) with respect to the Competitive Acquisition Program for Outpatient Drugs and Biologicals Under Part B (CAP) and revision to payment policies under the Physician Fee Schedule. Biogen Idec is a global leader in biotechnology headquartered in Cambridge, Massachusetts. Our products and development programs have addressed a variety of key medical needs in the areas of oncology, neurology, dermatology, and rheumatology.

Biogen Idec's pipeline and existing products are infused or injected in a variety of settings, including physician offices. Medicare beneficiaries depend upon advancements in biologic therapies to fight life-threatening conditions such as cancer, as well as chronic, debilitating conditions such as Multiple Sclerosis. Physicians, however, will provide these products in the office setting only if Medicare's payment rates adequately cover physicians' expenses for the financial and administrative costs of acquiring and administering them. Biogen Idec is pleased that CMS resumed implementation of the CAP so that physicians have more flexibility in acquiring necessary drugs and biologicals, and we urge CMS to take any necessary steps to ensure that physicians are adequately reimbursed for drug administration services whether they elect CAP or the ASP system.

Biogen Idec appreciates CMS' significant ongoing efforts to engage the provider, beneficiary, and manufacturer communities in open dialogues to shape payment policy reforms. We urge the agency to continue to work with these stakeholders to ensure accurate and adequate payment rates for these important components of beneficiary health care. Similarly, Biogen Idec supports CMS as it faces the challenge of developing a long-term physician fee schedule approach that ensures adequate physician payment while promoting high quality and value in health care for Medicare beneficiaries. We offer our comments to encourage CMS in continuing its creative approach toward implementing payment reforms without disrupting access to care. Through its Demonstration authority, CMS has begun to explore the concept of value-based payment systems for oncology providers. Biogen Idec expects that beneficiaries who suffer from rare, chronic debilitating disorders such as Multiple Sclerosis may benefit from similar initiatives and we would appreciate opening a dialogue with CMS in the future regarding any pending or potentially beneficial programs for these patient groups.

We have focused our comments on the ASP issues presented in the proposed and final rules, the adequacy of payment rates for drug administration services (including implementation of the new CPT codes), revisions to calculation of the Sustainable Growth Rate (SGR), and the CAP.

I. ASP

Biogen Idec applauds CMS for its decision to decline implementation of its proposal to require separate ASP calculations for direct and indirect sales. We understand that CMS intends to issue a final rule further refining and/or clarifying ASP calculation requirements and request that the agency permit notice and comment for any provisions that represent a departure from current methodologies.

Biogen Idec had previously commented on the threshold CMS articulated in its Proposed Rule for determining when to substitute WAMP or AMP for ASP. We noted that CMS had, in November 2004, opined that it was "premature to address the implementation issues prior to the OIG establishing its methodology and conducting its first review." We reiterate our concern that the OIG methodology, including sources of information, were not sufficiently illuminated to enable meaningful comment on the appropriateness of the 5% threshold. Biogen Idec concurs with the Biotechnology Industry Organization (BIO) in its belief that both notice of the methodology and opportunity for comment are required as part of the "procedural and substantive safeguards to ensure the reliability and validity of the data" for determining when to use WAMP or AMP instead of ASP.[1]

Biogen Idec is further concerned that the exemption from ASP calculations for sales to CAP vendors articulated in a separate rulemaking to encourage discounts in the initial phase of the

[1] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, H.R. Rep. No. 108-391, at 592 (noting that the safeguards include "notice and comment rulemaking, identification of the specific sources of information used to make [a determination to use WAMP instead of ASP], and explanations of the methodology and criteria for selecting such sources"

CAP may become meaningless if CMS substitutes WAMP for ASP in future years and the WAMP calculation includes CAP sales.

II. Ensuring Appropriate Payment for Drug Administration Services

CMS stated that it anticipates that the 2006 changes to the CPT coding system for drug administration services should mitigate the impact of eliminating the MMA transition payment add-ons for these services. We agree that the greater granularity in codes will prove helpful to physicians, yet remain concerned that CMS does not yet have the utilization data necessary to adequately value these services. While CMS has sought and received insight from the AMA and a number of specialty societies, through surveys and other materials, that data does not match to the granularity of the new coding set.

The MMA directed CMS to examine the cost of administration services by focusing on high infusion volume specialties. Biogen Idec remains concerned that for treatment innovations in specialties for which infusion services are a relatively low percentage of services, the impact of inadequate payment rates falls on beneficiaries in the form of constricted access. As novel treatments are discovered and brought to market, physicians in these specialties will be faced with the decision of whether or not the addition of in-office infusion capability is economically feasible. Inadequate reimbursement for the office resources required to administer these therapies will result in beneficiaries facing the risk of dropping out of their healthcare regimen, and force those seeking newer treatments to search for willing providers outside the specialty of their treating physician, or in the hospital outpatient departments. This fragmentation of care is inefficient for the Medicare program, as it likely will increase the number of patient office visits. It also compromises the physician/patient relationships essential to a value-based health care system. Biogen Idec urges CMS to ensure that its reimbursement levels for administration of drugs and biologicals is sufficient to enable providers to introduce infusion services as new treatments become available.

Biogen Idec also notes that CMS implemented the 2006 CPT codes for drug administration services through G codes in 2005. CMS contractors implemented these codes by making contractor-specific determinations of the drugs and biologicals for which administration could be coded with the higher payment chemotherapy codes. Many contractors implemented CMS instructions very narrowly, and limited the expanded definition of chemotherapy that was intended to include administration of complex biological therapies such as "monoclonal antibodies and other biologic response modifiers" to monoclonal antibodies alone. Biogen Idec urges CMS to instruct its contractors to discontinue use of the G code lists rather than to implement them for the new CPT codes. This would be consistent with CMS' long-standing policy of deferring to the AMA on CPT coding interpretation.

III. Sustainable Growth Rate (SGR)

CMS noted in its Proposed Rule that changes in the fee schedule, including the propose 4.3% reduction in the conversion factor, the expiration of the MMA's transitional adjustment for drug administration services, and the end of the oncology services demonstration program would significantly reduce Medicare payments to physicians. Through 2006, CMS will be under greater pressure than ever as advances in diagnostic and therapeutic standards of care, together with a growing Medicare population, create a tension between the immediate cost and long-term cost efficiency of health care for the elderly and disabled population. Biogen Idec expects that the legislative provision to set the 2006 SGR adjustment at 0% will alleviate some of the uncertainty that physicians face with respect to continuing Medicare participation, but remains concerned that without continuing legislative intervention substantial payment cuts are almost inevitable.

Biogen Idec recognizes that Congress has provided for a MedPAC report to examine alternatives to the SGR methodology. While the report is a much-needed step, it will not be available to Congress or CMS until mid-2007. Biogen Idec urges CMS to work with physician groups and Congress to identify options to stabilize physician payment rates at adequate levels. Continued cuts in physician payment for drugs and their administration, combined with similar reimbursement cuts in the hospital outpatient setting could result in delayed interventions that, in the long-term, compel the costly health care inefficiencies the Administration seeks to eliminate.

IV. Competitive Acquisition Program for Drugs and Biologicals under Part B (CAP)

Biogen Idec is pleased that CMS has resumed implementation of the CAP. Specifically, we believe that many refinements to the CAP that were explained in the Final Rule will eradicate potential barriers to vendor and physician participation. We appreciate CMS' clarification of its policy regarding CAP payment for unused portions of single-use vials. Under this policy, the unused portion of a drug remaining in a single-use vial will be deemed to have been administered for CAP purposes of the CAP if the "participating CAP physician has made good faith efforts to minimize the unused portion of the CAP drug in how he or she scheduled patients, and how he or she ordered, accepted, stored, and used the drug."[2] In addition, the CAP vendor must make "good faith efforts to minimize the unused portion of the drug in how it supplied the drug."[3] This policy is consistent with that for drugs reimbursed under the ASP system so that physicians electing CAP will not have an added burden of complying with complicated unused drug requirements.

Biogen Idec is also pleased that CMS will permit physician/vendor contractual arrangements to streamline claims processing and minimize the administrative burden for CAP participants. We suggest, however, that CMS provide physicians and vendors with greater clarity on any

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2 70 Fed. Reg. at 70248.

3 Id.

constraints with arrangements such as physician collection of drug copayments. For example, it is unclear whether the physician must wait until the physician service claim has been paid, or if the office can collect the copayment at the time of administration and then submit it to the vendor after the claim has been processed.

Biogen Idec also appreciates CMS' efforts to ensure that physicians are able to access new drugs and biologics through CAP at the earliest opportunity. This flexibility is especially important to the non-oncology providers that have expressed a strong interest in electing CAP as an alternative to the ASP model. Biogen Idec, and its partner, Elan, are hopeful that the novel MS therapy TYSABRI (natalizumab) will be commercially available again during 2006. Although the CMS HCPCS committee declined to issue a permanent J code for 2006, CMS officials assured Elan that the HCPCS decision would not have any negative impact on TYSABRI given the 2005 issuance of a product-specific Q code. We expect that CAP vendors may wish to offer TYSABRI when it returns to market, and that they will be able to receive approval from CMS to do so once the agency has re-established an ASP.

Conclusion

Biogen Idec appreciates the opportunity to comment on the important policy changes contained in the Final Rule. We look forward to working with you to ensure that Medicare beneficiaries retain appropriate access to medically necessary therapies. If you have any questions or comments, or need additional information, please do not hesitate to contact me.

Very truly yours,

Brian McGinty
Vice President
Managed Markets and Reimbursement

Submitter : **Dr. Michael Repka** **Date: 01/03/2006**

Organization : **American Academy of Ophthalmology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-1502-FC-67-Attach-1.DOC

CMS-1502-FC-67-Attach-2.PDF

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

Suite 700
1101 Vermont Avenue NW
Washington, DC 20005-3570

Tel. 202.737.6662
Fax 202.737.7061
http://www.aao.org

Federal Affairs Department

January 3, 2006

via Electronic Mail
Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

RE: CMS-1502-FC (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Final Rule with Comment)

Dear Dr. McClellan:

On behalf of the American Academy of Ophthalmology (Academy) I am writing to comment on the final Medicare Program Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006. The Academy is the world's largest organization of eye physicians and surgeons, with more than 27,500 members. Over 16,000 of our members are in active practice in the United States. We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) final rule.

The Academy would like to take this opportunity to provide CMS with additional information as requested in the final rule and to express our gratitude to CMS for withdrawing its proposal to implement changes to the 2006 physician fee schedule based on modifications of the practice expense methodology used to calculate physician fees. The Academy would also like to commend CMS on its changes to the method for revising malpractice RVUs, and would encourage CMS to continue working on a solution to resolve continuing problems with the SGR. The Academy urges CMS to consider and subsequently adopt the recommendations included in this comment letter and appreciates the opportunity to comment.

PE Methodology Changes

The Academy was pleased with CMS's decision to withdraw its proposal to implement changes to the practice expense (PE) methodology. We are very supportive of the decision to hold-off on implementation of any changes and further commend CMS on its planned efforts to further clarify the method underlying any indirect PE cost methodology changes by working through these issues with the medical community. We are confident that efforts on

the part of CMS to further clarify its PE proposal would be beneficial to all medical specialties and would allow each specialty to adequately assess the impact of any PE changes prior to implementation of a new methodology. We are also supportive of CMS's efforts to correct its program to ensure that the indirect PE costs portion of the PE RVUs is accurately calculated. The Academy supports CMS's decision to not use accepted supplementary data in indirect PE calculations for 2006. The Academy looks forward to working with CMS over the next year to develop a more accurate methodology for fairly assessing PE costs.

Miscellaneous PE Issues: Pricing of New Supply and Equipment Items

The Academy applauds CMS's continuing efforts to update the supplies and equipment used in determining the practice expense values attributed to individual CPT codes. In response to the final rule we are providing CMS with additional information and documentation (see enclosures) substantiating the cost of EQ271 Radiuscope. We are also providing additional information regarding the cost of SJ073 DMV Remover (see enclosures). We appreciate the opportunity to provide CMS with additional information regarding this equipment and supply and anticipate that CMS will now have adequate information to finalize the values for these items.

Table 14- Supply Items Needing Specialty Input for Pricing
SJ073 DMV Remover (associated with 92310-92317) -- The DMV remover, Ultra I is available through Bernell at a total cost of $19.95 (box of 10).

The Bernell Corporation may be contacted at:
4016 N. Home Street
Mishawaka, IN 46545
1-800-348-2225
www.bernell.com

Table 15- Equipment Items Needing Specialty Input for Pricing and Proposed Deletions
EQ271 Radiuscope (associated with 92310-92317)-- The Radiuscope, MARCO; Lombart Part #5005 is available through Lombart Instruments at a total cost of $1595.

Lombart Instruments may be contacted at:
5358 Robin Hood Road
Norfolk, VA 23513
1-800-446-8092
ATTN: Jon Pierce

Malpractice Relative Value Units (RVUs):

2. Specialty Crosswalk Issues
The Academy commends CMS's decision to assign optometrists and opticians a malpractice risk factor of 1.0. As we stated in our comments on the 2005 rule, we believe that a specialty's malpractice risk factor should reflect the actual level of malpractice risk

assumed during the performance of procedures. The proposed changes in the malpractice crosswalks are a positive step in this direction.

4. Dominant Specialty for Low-Volume Codes

The Academy continues to urge CMS to reconsider use of the dominant specialty approach in calculating the malpractice RVUs for services and procedures with fewer than 100 occurrences. However, it is important to note that if a procedure is performed fewer than 100 times the percentages of those providing it, outside of the majority, constitutes a very small percentage of providers. Allowing a potentially very low number of providers to have a significant impact in determining the malpractice risk factor RVUs associated with a procedure may lead to distortion of the actual risk involved. Therefore, we continue to advocate for the dominant specialty approach for procedures meeting this criteria and encourage CM<S to continue working with the RUC's PLI Workgroup on this issue.

Coverage of Glaucoma Screening

The Academy commends CMS on its decision to expand the high risk glaucoma category to include Hispanic Americans age 65 and older.

Including Hispanic Americans in the high-risk category will spearhead glaucoma prevention efforts and should help diminish the rate of severe vision loss due to this disease.

SGR

The Academy urges CMS to continue to take steps to halt projected physician fee cuts in 2006 and future years caused by continuing problems with the SGR formula.

Physicians continue to confront the reality of trying to provide high quality services to patients in the face of continued fee schedule cuts. Many of the issues underlying these fee cuts could be resolved by correcting the SGR formula. The Academy urges CMS to be proactive in resolving ongoing issues with the SGR by excluding Part B drug spending from physician service spending thereby freeing up money for physician fees by reducing the gap between actual and target spending.

Drug products are not a physician service and should not be included in the SGR pool. Leaving these costs in the pool does not counter-balance incentives for over-utilization, especially in light of the significant cuts in drug payments as a result of the Medicare Modernization Act. The Academy along with the AMA and other medical associations has provided CMS with legal analysis in support of our position on this issue. Taking immediate steps to fix the SGR formula by removing physician administered drugs from the pool will help stabilize anticipated cuts in already diminished physician fees thereby ensuring continued beneficiary access to quality health care.

Conclusion

The Academy urges CMS to give serious consideration to the comments raised in this letter. We thank CMS for withdrawing its PE methodology proposal. The Academy also thanks CMS for accepting supply and equipment pricing information submitted with the proposed rule comments and encourages CMS to accept the supply and equipment pricing information submitted with this letter for inclusion in the PE database. The Academy continues to support CMS's decision to include Hispanic Americans among the group of individuals at high risk for developing glaucoma. Lastly, we urge CMS to remove physician administered drugs from the SGR.

Again, the Academy would like to thank you for providing us with the opportunity to comment and looks forward to CMS's response.

Sincerely,

Michael X. Repka, M.D.
Secretary of Federal Affairs

Enclosures

MARCO

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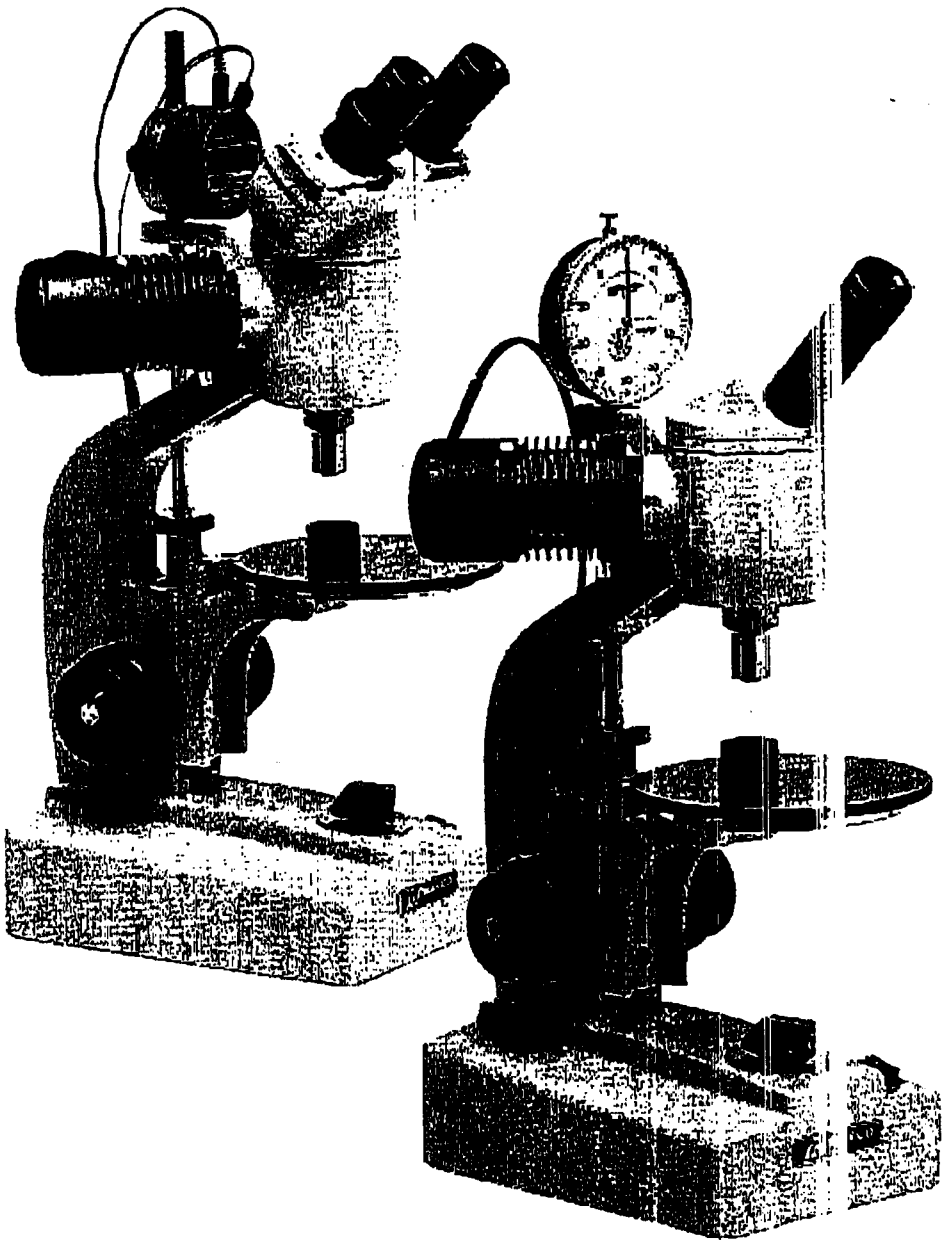

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The accuracy of both measurements is increased through the 100x magnification and a coaxial coarse and fine focusing knob.

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- Variable voltage transformer incorporated into base of unit.
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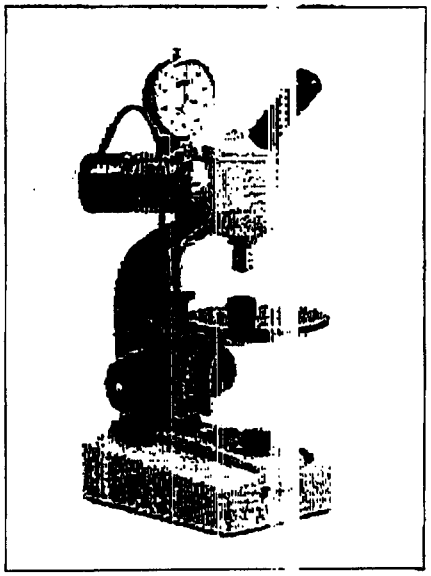
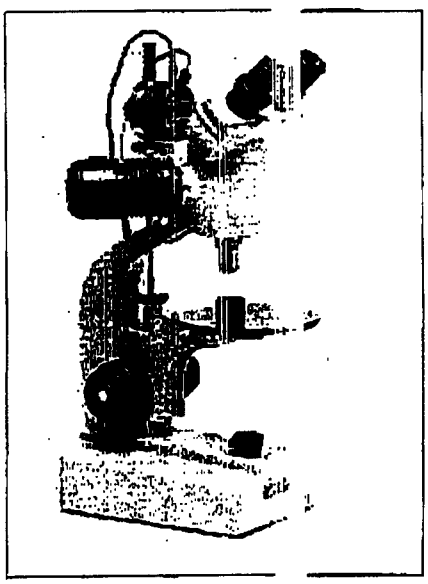
- Compact, modern design, simple to use.

Dimensions:	Height:	19"
	Depth:	10"
	Width:	8"
	Weight:	Approximately 13 pounds.
	Color/Finish:	Grey.



Monocular Radiusgauge



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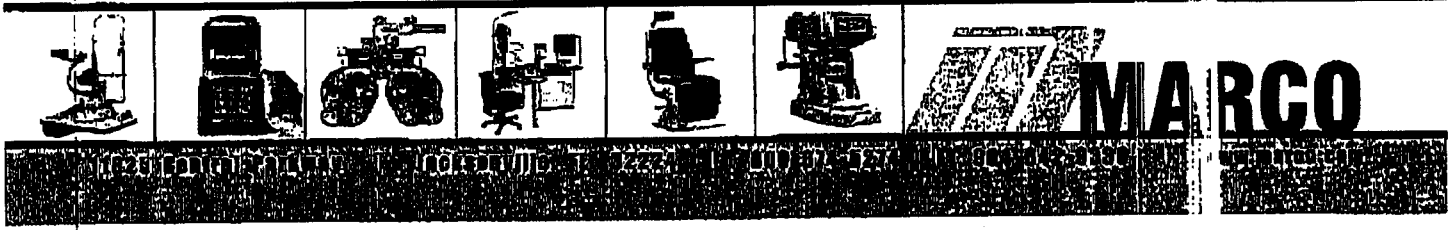

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SPECIFICATIONS & FEATURES

- Measurement of contact lens curvature and thickness.
- Standard 100x magnification with 10x objective and 10x eyepiece.
- Large external dial gauge.
- Coaxial coarse and fine focusing.
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- Variable voltage transformer incorporated into base of unit.
- Monocular or binocular.
- Standard or digital gauge
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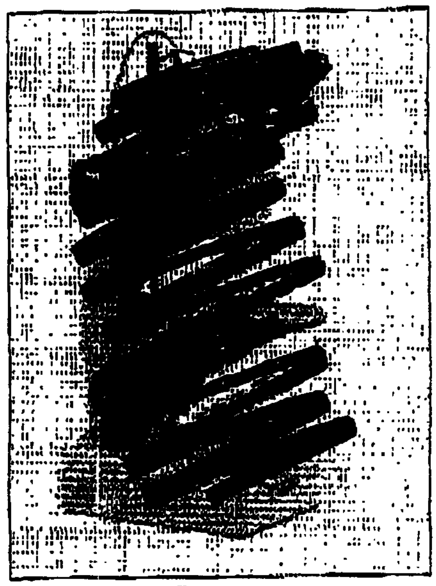
Dimensions:	Height:	19"
	Depth:	10"
	Width:	8"
	Weight:	Approximately 13 pounds.
	Color/Finish:	Grey.



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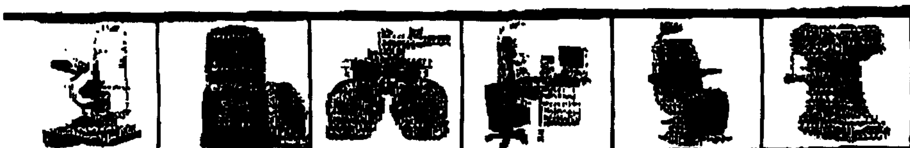

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TOTAL P.12

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About Bernell

Internet Specials!

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What is Vision Therapy?

International sales:

Bernell is happy to sell directly to you, but you may prefer to use one of our overseas distributors. There is an export handling fee added to the actual shipping charges when ordered directly. You are responsible for any import duties. Our foreign distributors have already paid the duties and shipping. They keep many of our products in stock.

See a list of our Foreign Distributors

When placing an direct foreign order, please email us at amartin553@aol.com to tell

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or email Al Martin, VP of Operations, at amartin553@aol.com

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See CL Reticules /Comparators on page 38

Contact Lens Vial Crimper

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Poster Soft Contact Lens Wet Cell

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BC7009 . . . . . **$19.95**

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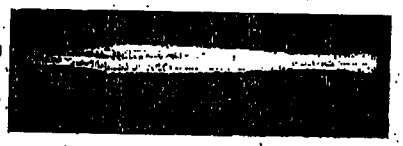
Handles soft contact lenses without tearing, scratching or marring. Insertion and removal available from a vertical or horizontal position. For hygiene reasons, non-returnable.

DMVSLH **$7.95**

CL Forceps

These forceps work well on either end. The tip is round so that it doesn't puncture a soft lens. The flat tip also keeps the CL from folding over and sticking on itself. The other end is round and flat and allows the lens to cling from the bottle.



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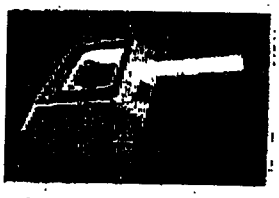

WEC16401 . . . . . **$229.95**

Replacement Ultraviolet Tubes. Used in Burton, S/Y Ultraviolet Lamps, or Luxo Ultraviolet Lamp.

WEF4T5BLB Ultraviolet Tube **$7.95**
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Ultra CL Handlers

Flexible plastic 7mm cup. Two model choices for hard contact lenses. For hygiene reasons, non-returnable.

ULTRA I

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DMVI (box of) **$19.95**

ULTRA II

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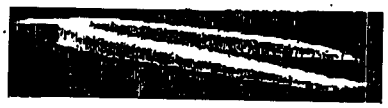
Soft Contact Lens Tweezer



White polypropylene tweezer 5" long x 1/2" wide. Rubberized tips for delicate handling. For hygiene reasons, non-returnable item.

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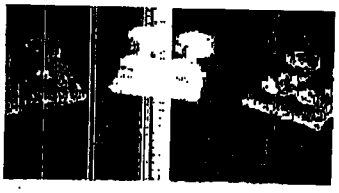

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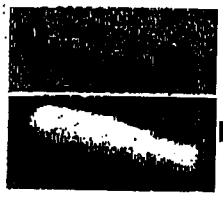

Design minimizes warping and cylinders in lens, while holding. Fits the Stronghold bulb. Available in Green Rubber or White Vinyl.

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Submitter : Dr. Michael Repka

Organization : American Academy of Ophthalmology

Category : Health Care Professional or Association

Date: 01/03/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachments (supercedes prior submission on 1/3/06: temporary comment 44830)

CMS-1502-FC-68-Attach-1.DOC

CMS-1502-FC-68-Attach-2.PDF

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

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Washington, DC 20005-3570

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Federal Affairs Department

January 3, 2006

via Electronic Mail
Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

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Table 15- Equipment Items Needing Specialty Input for Pricing and Proposed Deletions
EQ271 Radiuscope (associated with 92310-92317)-- The Radiuscope, MARCO; Lombart Part #5005 is available through Lombart Instruments at a total cost of $1595.

Lombart Instruments may be contacted at:
5358 Robin Hood Road
Norfolk, VA 23513
1-800-446-8092
ATTN: Jon Pierce

Malpractice Relative Value Units (RVUs):

2. Specialty Crosswalk Issues
The Academy commends CMS's decision to assign optometrists and opticians a malpractice risk factor of 1.0. As we stated in our comments on the 2005 rule, we believe that a specialty's malpractice risk factor should reflect the actual level of malpractice risk

assumed during the performance of procedures. The proposed changes in the malpractice crosswalks are a positive step in this direction.

4. Dominant Specialty for Low-Volume Codes

The Academy continues to urge CMS to reconsider its decision not to use the dominant specialty approach in calculating the malpractice RVUs for services and procedures with fewer than 100 occurrences. However, it is important to note that if a procedure is performed fewer than 100 times the percentages of those providing it, outside of the majority, constitutes a very small percentage of providers. Allowing a potentially very low number of providers to have a significant impact in determining the malpractice risk factor RVUs associated with a procedure may lead to distortion of the actual risk involved. Therefore, we continue to advocate for the dominant specialty approach for procedures meeting this criteria and encourage CM<S to continue working with the RUC's PLI Workgroup on this issue.

Coverage of Glaucoma Screening

The Academy commends CMS on its decision to expand the high risk glaucoma category to include Hispanic Americans age 65 and older.

Including Hispanic Americans in the high-risk category will spearhead glaucoma prevention efforts and should help diminish the rate of severe vision loss due to this disease. We look forward to working with CMS in publicizing the new benefit to this at risk population.

SGR

The Academy urges CMS to continue to take steps to halt projected physician fee cuts in 2006 and future years caused by continuing problems with the SGR formula.

Physicians continue to confront the reality of trying to provide high quality services to patients in the face of continued fee schedule cuts. Many of the issues underlying these fee cuts could be resolved by correcting the SGR formula. The Academy urges CMS to be proactive in resolving ongoing issues with the SGR by excluding Part B drug spending from physician service spending thereby freeing up money for physician fees by reducing the gap between actual and target spending.

Drug products are not a physician service and should not be included in the SGR pool. Leaving these costs in the pool does not counter-balance incentives for over-utilization, especially in light of the significant cuts in drug payments as a result of the Medicare Modernization Act. The Academy along with the AMA and other medical associations has provided CMS with legal analysis in support of our position on this issue. Taking immediate steps to fix the SGR formula by removing physician administered drugs from the pool will help reduce anticipated cuts in already diminished physician fees thereby ensuring continued beneficiary access to quality health care.

Conclusion

The Academy urges CMS to give serious consideration to the comments raised in this letter. We thank CMS for withdrawing its PE methodology proposal. The Academy also thanks CMS for accepting supply and equipment pricing information submitted with the proposed rule comments and encourages CMS to accept the supply and equipment pricing information submitted with this letter for inclusion in the PE database. The Academy continues to support CMS's decision to include Hispanic Americans among the group of individuals at high risk for developing glaucoma. Lastly, we urge CMS to remove physician administered drugs from the SGR.

Again, the Academy would like to thank you for providing us with the opportunity to comment and looks forward to CMS's response.

Sincerely,

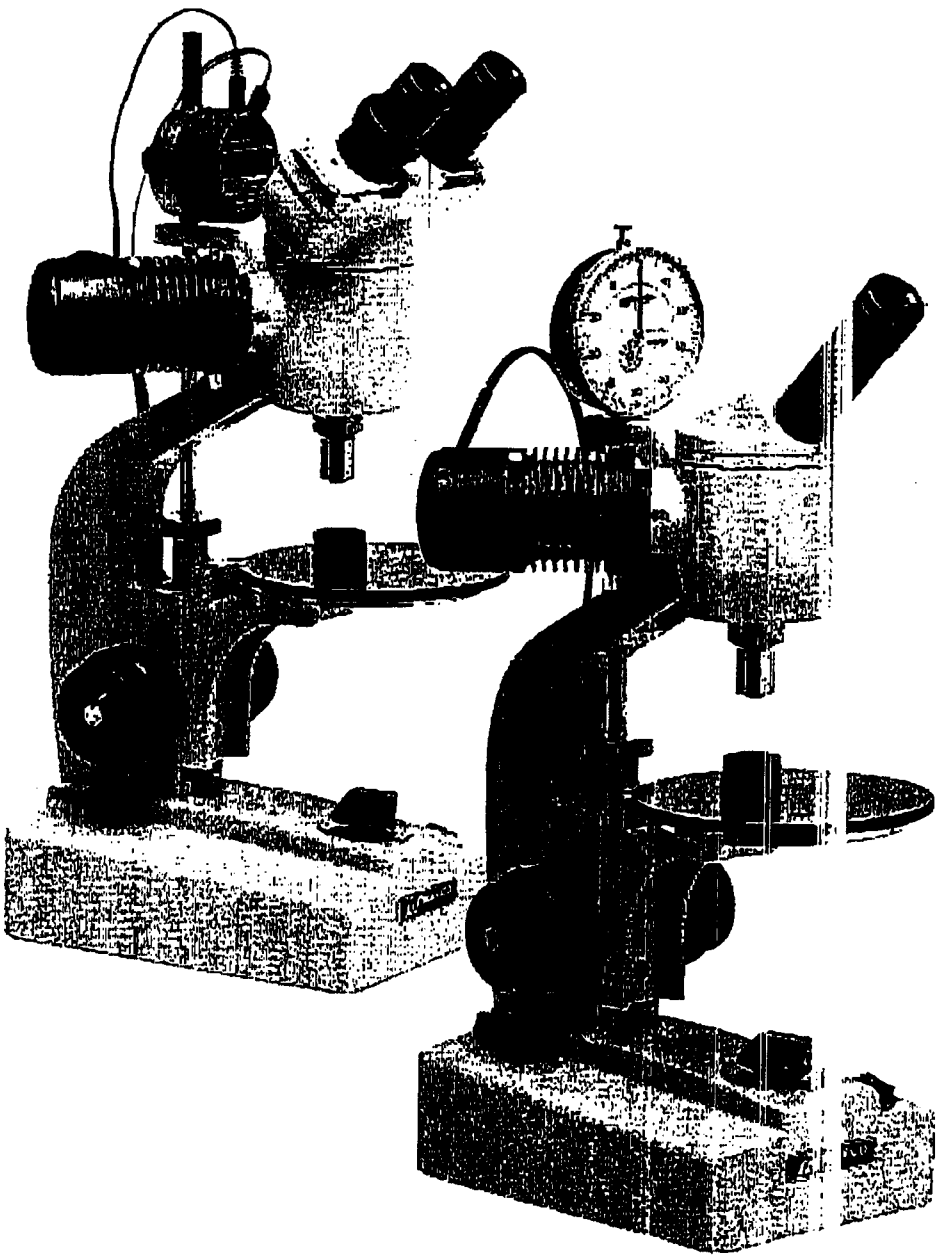
Michael X. Repka, M.D.
Secretary of Federal Affairs

Enclosures

MARCO

THE LEADER IN VISION DIAGNOSTICS

STANDARD RADIUSGAUGES



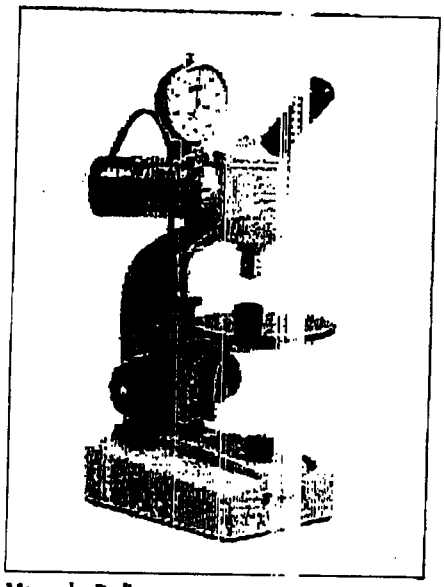
MARCO RADIUSGAUGES are available with either a standard or digital gauge as well as in either monocular or binocular form. All offer the functions of two instruments in one, measuring both the curvature and thickness of contact lenses on a single instrument.

The accuracy of both measurements is increased through the 100x magnification and a coaxial coarse and fine focusing knob.

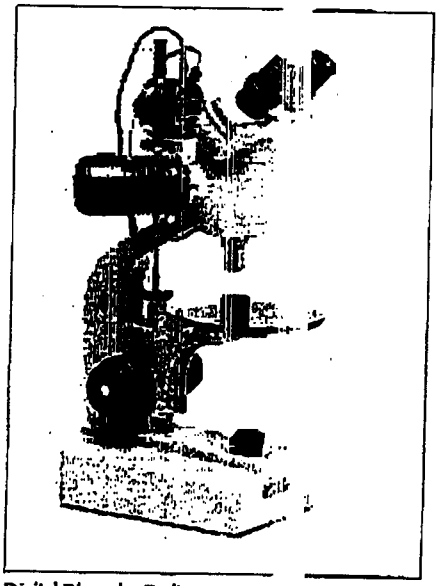
SPECIFICATIONS & FEATURES

- Measurement of contact lens curvature and thickness.
- Standard 100x magnification with 10x objective and 10x eyepiece.
- Large external dial gauge.
- Coaxial coarse and fine focusing.
- Large or small aperture.
- Variable voltage transformer incorporated into base of unit.
- Monocular or binocular.
- Standard or digital gauge
- Compact, modern design, simple to use.

Dimensions:	Height:	19"
	Depth:	10"
	Width:	8"
	Weight:	Approximately 13 pounds.
	Color/Finish:	Grey.



Monocular Radiusgauge



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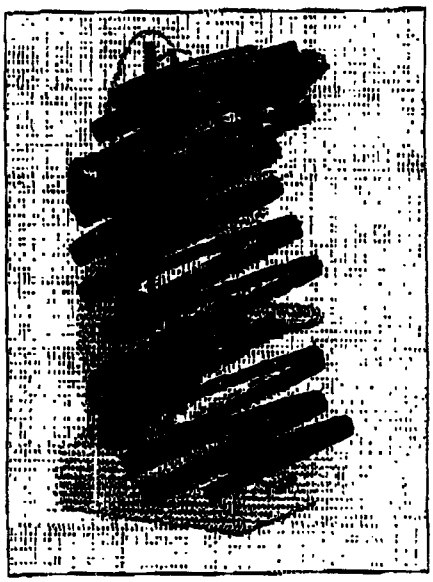
The accuracy of both measurements is increased through the 100x magnification and a coaxial coarse and fine focusing knob.

SPECIFICATIONS & FEATURES

- Measurement of contact lens curvature and thickness.
- Standard 100x magnification with 10x objective and 10x eyepiece.
- Large external dial gauge.
- Coaxial coarse and fine focusing.
- Large or small aperture.
- Variable voltage transformer incorporated into base of unit.
- Monocular or binocular.
- Standard or digital gauge
- Compact, modern design, simple to use.

Dimensions:	Height:	19"
	Depth:	10"
	Width:	8"
	Weight:	Approximately 13 pounds.
	Color/Finish:	Grey.

Monocular Radiusgauge



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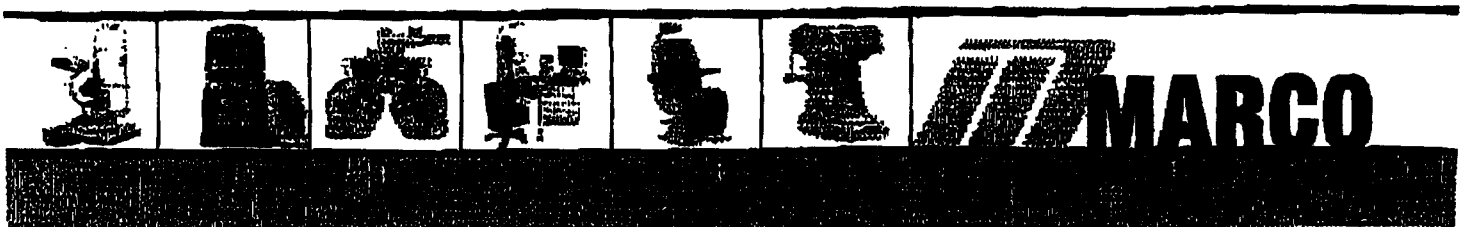

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or email Al Martin, VP of Operations, at amartin553@aol.com

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See CL Reticules /Comparators on page 38

CONTACTS

Contact Lens Vial Crimper

A handy tool that will last a lifetime. Allows you to recrimp existing or replace vial seals (caps available below) in one motion. Constructed of a rugged metal with a large sure-grip handle.

BH2002 .....**$99.95**

Vial Caps

Silver soft contact lens vial caps.

USOCAPS (500). **$12.95**
USOCAPS100 (100). . . . **$2.99**

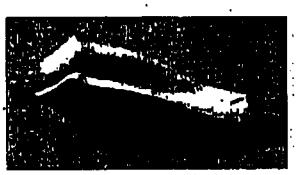
Poster Soft Contact Lens Wet Cell

Compact holder of transparent plexiglass. For the inspection and neutralization of soft lenses. Wet-state inspection; saline solution is poured into well (lens will float), place partially dried lens on 10mm hole (beveled edges) to inspect in the dry state.

BC7009 . . . . . **$19.95**

Soft Lens Handler

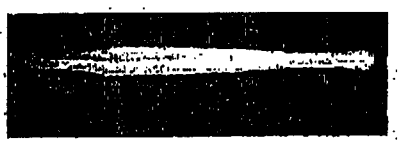
Handles soft contact lenses without tearing, scratching or marring. Insertion and removal available from a vertical or horizontal position. For hygiene reasons, non-returnable.



DMVSLH **$7.95**

CL Forceps

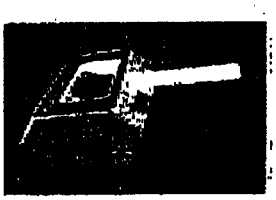
These forceps work well on either end. The tip is round so that it doesn't puncture a soft lens. The flat tip also keeps the CL from folding over and sticking on itself. The other end is round and flat and allows the lens to cling from the bottle.



USO7020. . . . . **$2.25**
5+. **$1.75**

Ultraviolet Light with Magnifier

3x ultraviolet examination and inspection light with 2" x 4" magnifying lens. Includes: 3-conductor cord set, two ultraviolet black lights and two fluorescent white lights.



WEC16401 . . . . . **$229.95**

Replacement Ultraviolet Tubes. Used in Burton, S/Y Ultraviolet Lamps, or Luxo Ultraviolet Lamp.

WEF4T5BLB Ultraviolet Tube **$7.95**
WEF4T5CW Cool White Bulb **$3.95**

Ultra CL Handlers

Flexible plastic 7mm cup. Two model choices for hard contact lenses. For hygiene reasons, non-returnable.

ULTRA I

Shaped to create natural suction. No air suction.

DMVI (box of 1) **$19.95**

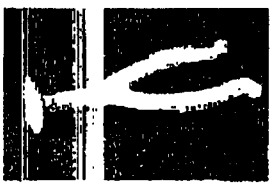
ULTRA II

Same shape, but has air duct through center open to insert; closed by squeezing to remove.

DMVII (box of 1) . . . **$19.95**

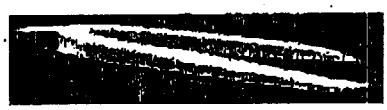
LENS EZE™

Soft CL Inserter/Remover makes lens handling easy. Pliable inserter cup holds thin lenses in correct shape; prevents thick lenses from falling. Positive tweezer-like action. For hygiene reasons, these are non-returnable.



I3 (pkg. of 3) **$13.95**
(dozen) **$60.00**

Soft Contact Lens Tweezer



White polypropylene tweezer 5" long x 1/2" wide. Rubberized tips for delicate handling. For hygiene reasons, non-returnable item.

USO7017. . . . . 3+@ **$1.99**
1-2 . . . . . **$2.25**

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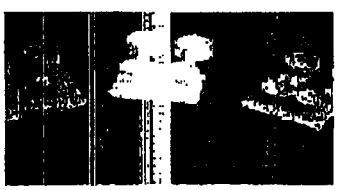

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100 . . . . . @ **30¢**
50 . . . . . @ **36¢**

Please specify color when ordering.

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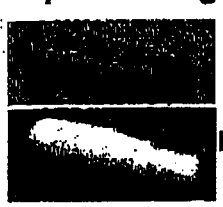

Design minimizes warping and cylinders in lens, while holding. Fits the stronghold bulb. Available in Green Rubber or White Vinyl.

DMVSSW Vinyl, White. **$4.25**
DMVSSG Rubber, Green **$4.25**

Prosthesis Remover

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DMVER **$2.35**

Stopper Popper

The task of removing vial caps is made easy. Made of rustproof stainless steel. No sharpening needed.

CA1 . . . . . **$9.95**

Submitter : **Mr. Jeff Bush** **Date: 01/03/2006**

Organization : **Becton, Dickinson and Company**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1502-FC-69-Attach-1.DOC

January 3, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
Room 445–G, HHH Bldg
200 Independence Ave., SW
Washington, DC 20201

Re: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006, Final Rule with Comment, November 21, 2005 (CMS-1502-FC)

Dear Dr. McClellan,

Becton, Dickinson and Company (BD), a medical technology company that serves healthcare institutions, life science researchers, clinical laboratories, industry and the general public, through the manufacture and sale of medical supplies, devices, laboratory equipment and diagnostic products, submits the following comments to the Centers for Medicare and Medicaid Services (CMS) regarding the Interim Final Rule: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 [CMS-1502-FC].

Our comments below specifically relate to CMS payment policies for flow cytometry testing and practice expense RVU's related thereto.

Brief Background

BD has submitted extensive comments on this issue dating back to CMS-1429-FC, wherein CMS published initial values for flow cytometry practice expense, and most recently on CMS-1502-P in which we strongly supported the agency's proposal to reflect more comprehensive practice expense data compiled from a broader variety of stakeholders than had previously been contemplated for CPT codes 88184 and 88185.

In the final rule for 2005, we were concerned that CMS had valued new codes for flow cytometry (88184 and 88185) at too low a level with respect to practice expense based on our broad knowledge of the costs to providers for these items. Consequently, we worked with a variety of stakeholders and the agency to identify areas where the data may have been inadequate and where updated, more accurate data might be incorporated. Collectively, we identified three primary areas where the practice expense inputs lacked appropriate cost information: costs associated with instrumentation that were either missing or were underestimated, costs associated with reagent antibodies that were underestimated, and the staff type performing the testing was listed as a

technician, but is in fact a technologist that requires a significantly higher wage than a technician.

Following these communications with stakeholders and the agency, we were pleased to see that the issue was reflected in CMS-1502-P, the proposed rule for the 2006 physician fee schedule (PFS). In our view, the CMS proposal adequately addressed the issue and proposed a fair and equitable solution going forward into 2006 and beyond. In our comments related to 1502-P, we commended the agency for its proposed action, as, in our view, it would result in continued access by most Medicare beneficiaries to critical lymphoma and leukemia flow cytometry testing.

However, CMS-1502-FC, published in November 2005 introduced a new twist. While the technical merits of the proposed practice expense increases for codes 88184 and 88185 were not questioned in the rule, the technicality that the new methodology for practice expense determinations had generated a significant volume of comments was cited as rationale for making no actual change in practice expense for these codes.

BD Response

We are certainly extremely disappointed in this outcome, given that the agency was unwilling to address this issue as a correction notice to the 2005 rule (CMS-1429-FC). Rather than aggressively pursue a correction notice, our industry agreed that a correction in the 2006 rule would be acceptable under the assumption that changes in practice expense would return payment to a level commensurate with the typical costs incurred. The effect of freezing practice expense, however, allows CMS to continue payment at the same troubling level from 2005 through the foreseeable future, despite essential agreement that the data upon which 2005 payments were calculated was flawed and should be revised. Furthermore, flow cytometry practitioners have advised us that this policy will have a very negative effect on lymphoma and leukemia flow cytometry testing access because they cannot afford to offer the testing at a loss.

We feel compelled to also challenge the premise upon which the practice expense freeze was applied to codes 88184 and 88185 pursuant to comments on CMS-1429-FC. Because of the nature of the coding processes and fee schedule timing, we understand and accept that the November rule each year must be a final rule with comment period. However, given this, we strongly believe that comments and any actions pursuant to those comments should be reflected as though they were implemented along with the final rule upon which the comments were made. I.e., in a normal rulemaking process, we would have had opportunity to raise the issues and have any resolutions reflected in the final rule. Since that is not an option in this rulemaking process, comments and decisions related to those comments ought to be implemented in a retroactive fashion bask to the beginning of the period in which the final rule became effective.

To this effect, we acknowledge that there are significant concerns with the practice expense methodology proposed in CMS-1502-P, but we respectfully submit that those issues should not impact the resolution of an issue that extends back to CMS-1429-FC. Therefore, we believe that the changes to practice expense RVU's for codes 88184 and 88185 proposed in CMS-1502-P should be made because the freeze is related to a new issue raised in the rule; whereas, the issue with 88184 and 88185 relates back to comments on the previous final rule and therefore any changes technically ought to be treated as though they were in full effect throughout 2005 (even though in practice, we know they are not, again due to the nature of the fee schedule and coding processes).

BD Recommendation

Given all of the above information, we respectfully recommend that CMS publish a correction notice as soon as possible that increases practice expense RVU's for codes 88184 and 88185 to the levels proposed by the agency in CMS-1502-P. The agency should note that this change is appropriate because it is in response to comments and research the agency has received and conducted pursuant to CMS-1429-FC, and as such reflects changes technically effective for 2005 practice expense RVU's. Therefore, the change is not affected by the 2006 practice expense freeze.

We sincerely appreciate the opportunity to submit these comments and look forward to working with the agency to implement a fair and equitable solution to the issues raised.

Sincerely,

Jeff Bush
Corporate Director, Reimbursement
Becton, Dickinson and Company
2350 Qume Drive, San Jose, CA 95131 USA

Submitter : Dr. Bill Law, Jr., FACP, FACE **Date:** 01/03/2006

Organization : American Association of Clinical Endocrinologists

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached Word Document

CMS-1502-FC-70-Attach-1.DOC

CMS-1502-FC-70-Attach-2.DOC

CMS-1502-FC-70-Attach-3.DOC

American Association of Clinical Endocrinologists
1000 Riverside Avenue • Suite 205 • Jacksonville, Florida 32204
Phone (904) 353-7878 • Fax (904) 353-8185 • http://www.aace.com

January 3, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

RE: Medicare Programs: Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Final Rule. Comments submitted electronically to http://www.cms.hhs.gov/regulations/ecomments.

Dear Dr. McClellan:

The American Association of Clinical Endocrinologists (AACE) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Final Rule for Medicare Programs; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006, published in the November 21, 2005, Federal Register. Our comments focus on two issues: 1) education and training codes for patient self-management and 2) continuous glucose monitoring. These issues were discussed during a meeting we had with Dr. Edith Hambrick and Ms. Carolyn Mullen at CMS headquarters in Baltimore on December 21, 2005.

Education and Training for Patient Self-Management

AACE worked with the CPT Editorial Panel and the AMA/Specialty RVS Update Committee (RUC), to create three new timed-based codes and develop recommended work relative value units (RVUs) for education and training for patient self-management services. The three new CPT 2006 codes (98960, 98961 and 98962) describe services that must be prescribed by a physician and provided by a qualified non-physician health professional using a standardized curriculum. In the final rule, CMS announced that these new codes are not covered by Medicare. However, CMS did not support this determination with any rationale in the final rule and none was provided during our meeting with CMS staff.

AACE believes that these codes clearly come within the definition of a service "furnished as an incident to a physician's professional service" as defined in Section 1861(s) (2) (A) of the Act and, consequently, are covered under Medicare Part B. Furthermore, there is nothing in section 1862 of the Act which would exclude them from coverage.

It should also be noted that while CMS might consider 99211 to be an appropriate solution for coding and billing purposes for these educational sessions, it is clear that the

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Deleted: Medicare Payment Update¶ AACE continues to offer its support of the AMA, on behalf of organized medicine, to rectify the inequities created by the use of the sustainable growth rate (SGR). Continued utilization of this formula and failure to enact meaningful fixes to the system will negatively impact quality through limited access to care. ¶ ¶ Practice Expense Methodology ¶ AACE agrees that the practice expense methodology should continue to include direct inputs to be added to the professional component of services when these inputs are clearly identified as physician services. This should be ... [1]
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Deleted: Request for Change in Medicare Coverage Decision¶ ... [3]
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typical 5 minute patient interactions described by 99211 (e.g., blood pressure check) are not sufficient for the amount of time and work described in codes 98960-98962, which by definition are "each 30 minutes."

There should be no question about the clinical value of these services for patients with conditions such as diabetes and asthma where education and training have been demonstrated as contributing to improved health outcome, and where such services have been incorporated into naturally recognized clinical practice guidelines, including some developed and disseminated by the National Institutes of Health. Furthermore, these codes will improve access to proper medical care and prevent delayed disease complications. CMS already supports G0108 and G0109 codes and these codes extend that principle of providing and documenting nationally approved curricula for the improvement of our patients' health."

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Comment [Bart1]: Where does this quote begin?

While these G codes are of value in certain settings, they are rarely used by physicians in their office practices because of the significant administrative burden associated with their use. In light of CMS' commitment to improve the care of diabetic patients and the evidence showing that education improves clinical outcomes, we do not understand why CMS would not cover these clinically important services.

We note that the RUC spent a great deal of time reviewing the survey data presented by the American Association of Clinical Endocrinologists (AACE) and American Dietetic Association (ADA), and that the RUC is on record supporting our position that these would seem to fit into the Medicare statutory benefit category of 'incident to' services.

In summary, AACE believes patient education and training for self-management is a service covered by Medicare Part B and, therefore, should be paid under the Physician Fee Schedule. Further, coverage of these services will improve care for Medicare beneficiaries and reduce costs to the Medicare program. AACE, the RUC, and many other specialties support these sentiments and urge CMS to reconsider its action of not covering these services under Medicare.

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Continuous Glucose Monitoring

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AACE worked with the AMA Relative Value Update Committee (RUC) to survey and develop work relative value unit (RVU) recommendations for CPT code 95251 *Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for up to 72 hours; physician interpretation and report.* The RUC recommended a work RVU of 0.85. In the final rule, CMS disagreed with this recommendation and published an interim work RVU of 0.52 stating that an appropriate reference service for this new procedure is 93268 *Patient demand single or multiple event recording with presymptom memory loop, 24-hour attended monitoring, per 30-day period of time; includes transmission, physician review and interpretation*

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Although the time period associated with cardiac event recording (CPT code 93268) is 30 days, the amount and complexity of data that needs to be reviewed for ambulatory continuous glucose monitoring (CPT code 95251) is considerably greater. As noted in the RUC's recommendations, ambulatory continuous glucose monitoring requires approximately 30 minutes of physician time, including interpretation of over 900 glucose values, overlaid with a patient log of several variables (caloric intake, physical activity, symptoms of hypo-, or hyper-glycemia, and other symptoms as they occur). Thus contiuous glucose monitoring interpretation is a four dimensional analysis as opposed to a two dimensional analysis with CPT code 93268.

We urge CMS to reconsider its decision concerning CPT 95251 and to assign the RUC recommended work value of 0.85 for this service.

Thank you for providing AACE the opportunity to comment. If we can be of further assistance, please do not hesitate to contact Shelley Garrett at 904-353-7878, ext. 142.

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Bill Law, Jr., MD, FACP, FACE
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supported the specialty society's recommendation of the 25th percentile of their survey, 0.85 work RVUs.

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Considering all of the aforementioned arguments, we urge CMS to reconsider its decision concerning CPT 95251 and to assign the RUC recommended work value of 0.85 for this service.

Page 1: [3] Deleted **Bart McCann** **1/3/2006 3:11:00 PM**

Request for Change in Medicare Coverage Decision

CMS has indicated various coverage decisions in its *Final Rule*. AACE would like to comment on the coverage decision pertaining to Education and Training for Patient Self-Management (CPT codes 98960-98962).

Education and Training for Patient Self-Management

Page 1: [4] Deleted **Bart McCann** **1/3/2006 3:16:00 PM**

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American Association of Clinical Endocrinologists
1000 Riverside Avenue • Suite 205 • Jacksonville, Florida 32204
Phone (904) 353-7878 • Fax (904) 353-8185 • http://www.aace.com

January 3, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244–8017

RE: Medicare Programs: Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Final Rule. Comments submitted electronically to http://www.cms.hhs.gov/regulations/ecomments.

Dear Dr. McClellan:

The American Association of Clinical Endocrinologists (AACE) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Final Rule for Medicare Programs; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006, published in the November 21, 2005, Federal Register. Our comments focus on two issues: 1) education and training codes for patient self-management and 2) continuous glucose monitoring. These issues were discussed during a meeting we had with Dr. Edith Hambrick and Ms. Carolyn Mullen at CMS headquarters in Baltimore on December 21, 2005.

Education and Training for Patient Self-Management

AACE worked with the CPT Editorial Panel and the AMA/Specialty RVS Update Committee (RUC), to create three new timed-based codes and develop recommended work relative value units (RVUs) for education and training for patient self-management services. The three new CPT 2006 codes (98960, 98961 and 98962) describe services that must be prescribed by a physician and provided by a qualified non-physician health professional using a standardized curriculum. In the final rule, CMS announced that these new codes are not covered by Medicare. However, CMS did not support this determination with any rationale in the final rule and none was provided during our meeting with CMS staff.

AACE believes that these codes clearly come within the definition of a service "furnished as an incident to a physician's professional service" as defined in Section 1861(s) (2) (A) of the Act and, consequently, are covered under Medicare Part B. Furthermore, there is nothing in section 1862 of the Act which would exclude them from coverage.

It should also be noted that while CMS might consider 99211 to be an appropriate solution for coding and billing purposes for these educational sessions, it is clear that the

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typical 5 minute patient interactions described by 99211 (e.g., blood pressure check) are not sufficient for the amount of time and work described in codes 98960-98962, which by definition are "each 30 minutes."

There should be no question about the clinical value of these services for patients with conditions such as diabetes and asthma where education and training have been demonstrated as contributing to improved health outcome, and where such services have been incorporated into naturally recognized clinical practice guidelines, including some developed and disseminated by the National Institutes of Health. Furthermore, these codes will improve access to proper medical care and prevent delayed disease complications. CMS already supports G0108 and G0109 codes and these codes extend that principle of providing and documenting nationally approved curricula for the improvement of our patients' health."

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While these G codes are of value in certain settings, they are rarely used by physicians in their office practices because of the significant administrative burden associated with their use. In light of CMS' commitment to improve the care of diabetic patients and the evidence showing that education improves clinical outcomes, we do not understand why CMS would not cover these clinically important services.

We note that the RUC spent a great deal of time reviewing the survey data presented by the American Association of Clinical Endocrinologists (AACE) and American Dietetic Association (ADA), and that the RUC is on record supporting our position that these would seem to fit into the Medicare statutory benefit category of 'incident to' services.

In summary, AACE believes patient education and training for self-management is a service covered by Medicare Part B and, therefore, should be paid under the Physician Fee Schedule. Further, coverage of these services will improve care for Medicare beneficiaries and reduce costs to the Medicare program, AACE, the RUC, and many other specialties support these sentiments and urge CMS to reconsider its action of not covering these services under Medicare.

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Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1502-FC
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CMS has indicated various coverage decisions in its *Final Rule*. AACE would like to comment on the coverage decision pertaining to Education and Training for Patient Self-Management (CPT codes 98960-98962).

Education and Training for Patient Self-Management

Page 1: [4] Deleted **Bart McCann** **1/3/2006 3:16:00 PM**

which made several recommendations for three new CPT 2006 codes 98960 , 98961 and 98962 which are timed codes describing education and training for patient self-management services prescribed by a physician and provided by a qualified non-physician health professional using a standardized curriculum.

Page 1: [5] Deleted **Bart McCann** **1/3/2006 3:17:00 PM**

The RUC spent a great deal of time reviewing the survey data presented by the American Association of Clinical Endocrinologists (AACE) and American Dietetic Association (ADA). The RUC supports the following comments from AACE, "AACE questions this coverage determination and would like to note that these services would seem to fit into the Medicare statutory benefit category of 'incident to' services.

Submitter : Mr. Hugh O'Neill
Organization : Sanofi-Aventis
Category : Drug Industry

Date: 01/03/2006

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1502-FC-71-Attach-1.DOC

CMS-1502-FC-71-Attach-2.DOC

Recognition of Comments Submitted on Proposed Rule

In our earlier letter of September 30, 2005, we submitted comments to the Centers for Medicare and Medicaid Services ("CMS") on the preceding proposed rule (CMS-1501-P). We commented on several areas and wish to thank CMS for certain decisions and to share some continuing concerns regarding others.First, thank you for deciding against proceeding with the proposed new requirement regarding direct and indirect sales reporting. As we and other commenters [illegible] [illegible]’ services. It is essential that Medicare payment policy recognize costs incurred by physicians in providing care to beneficiaries.

Continuing Issues

Separately, as noted in the opening of this letter, sanofi-aventis would like to offer additional comments that we request CMS consider as it develops policies for updated guidances and proposed rules for publication next Spring. These relate to the widely available market prices ("WAMP") methodology, CAP, and coding for sodium hyaluronate products issues.

1. **Widely Available Market Pricing Implementation**

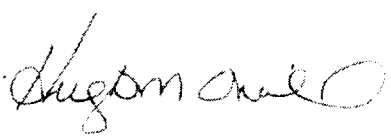
In our earlier comments, we raised a number of important definitional and procedural questions regarding CMS's planned implementation of the WAMP concept relative to otherwise applicable average sales price (ASP) payment policy methods for drugs and biologicals. Despite its fairly extensive preamble discussion around WAMP-related comments, CMS largely failed to answer these material questions. CMS instead deferred to the role of the OIG under the statute in carrying out surveys to determine WAMP levels for targeted products. In our view, despite the data collection role played by the OIG, interpretation and adaptation of the OIG's results to the Medicare program, including both policy and operational elements, are principally CMS's responsibility under Title XVIII. Therefore, we reiterate that we think it is very important that CMS implement WAMP through rulemaking, and provide opportunity for notice and public comment on the key policy and implementation decisions. In addition, we strongly urge the Agency to develop a consultative process by which, prior to public release of a proposed payment level, the Agency directly confirms the accuracy of pricing data used to create a proposed WAMP-based payment level for a product. This step will instill greater accuracy, avoid damaging errors and create a greater sense of fairness.

code, J7318, Hyaluronan (sodium hyaluronate) or derivative, intra-articular injection, 1 mg. Although we maintain that these agents should have separate codes, adopting a single code to cover all of the sodium hyaluronate (hyaluronan/hylan) products is the only other option that is defensible from the scientific and policy perspective provided that the code description includes "per injection" or "per dose". The code description provided by CMS would have resulted in payment disparities given that dosages for these products vary from 16 mg per injection to 30 mg per injection. There is no clinical evidence that supports a dose-response relationship for these products, therefore, we question the reason for basing payment on a per mg basis instead of a per injection basis.

The current coding and payment policy, which reversed the October decision, is not neutral. Maintaining the status quo is not fair to patients, physicians or those who develop these products. The current coding and payment policy provides financial incentives for physicians to choose one product over another, and under the CAP program, will limit access to certain products. We continue to believe that the appropriate coding and payment policy is to adopt product-specific codes for each of the single source products, to assign product-specific payments under the ASP-payment methodology, and to require CAP vendors to offer each one of these single source products. We would strongly encourage CMS to adopt product-specific codes and payments for each of the hyaluronans.

In closing, we thank you for your attention to these matters. If you have any questions, please feel free to contact me.

Respectfully Submitted,



Hugh O'Neill
Vice President, Integrated Healthcare Markets

Submitter : Dr. William Jessee

Date: 01/03/2006

Organization : Medical Group Management Association

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the final rule entitled the "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B," as published in the Nov. 21, 2005 Federal Register. We appreciate the Centers for Medicare & Medicaid Services? (CMS) outreach to the provider community and their willingness to participate in constructive dialogue to improve the Medicare program. We look forward to continuing our collaborative work on this and other administrative simplification issues. For these reasons, MGMA offers the following critiques and recommendations related to this rule, as outlined below.

SEE ATTACHED FOR REST OF COMMENT*

Interim Relative Value Units

Interim Relative Value Units

MGMA applauds CMS' decision to delay implementation of the new "bottom-up" methodology. MGMA welcomes the opportunity to continue to work with CMS in development of the new practice expense (PE) values. MGMA appreciates CMS' willingness to listen to industry concerns regarding the availability of the fully implemented data. This data are not widely understood, and sample PE RVU value calculations were not accurate, causing a further lack of clarity.

ALLERGAN

2525 Dupont Drive, P.O. Box 19534, Irvine, CA 92623-9534 • (714) 246-4500

January 3, 2006

VIA ELECTRONIC SUBMISSION

Mark McClellan, M.D., Ph.D. Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B; Final Rule
CMS-1502-FC and 1325-F
Interim Relative Values for new codes 64650 and 64653
Interim Relative Values for new code 46505
Interim Relative Values for new codes 95873 and 95874
Revised Practice Expense Relative Values for codes 64613 and 64614

Dear Dr. McClellan:

On behalf of Allergan Inc. ("Allergan"), we are pleased to submit comments in response to the above-captioned Final Rule with Comment Period ("Final Rule") on the Medicare Physician Fee Schedule ("Fee Schedule") for 2006. Allergan develops and manufactures BOTOX® (Botulinum Toxin Type A) Purified Neurotoxin Complex. BOTOX® is a biological used to treat patients with blepharospasm (a disorder involving involuntary closure of the eyelids), strabismus (a disorder of muscles that move the eyes), cervical dystonia (abnormal movements of the neck muscles) and severe primary axillary hyperhidrosis (disorder of sweat glands).[1] Botulinum toxin type A is administered by physicians in their offices and in hospital outpatient departments. Botulinum toxin type A is covered as a biological provided incident-to a physician's service under Medicare Part B.[2]

1. Interim Relative Values for New Codes 64650 and 64653

Administration of botulinum toxin type A comprises a chemodenervation procedure. The most common codes used to report chemodenervation procedures are: 64612, 64613 and 64614. These codes were

[1] The current package labeling includes the following indications for BOTOX®:
BOTOX® is indicated for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia.
BOTOX® is indicated for the treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents.
BOTOX® is indicated for the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above.
The efficacy of BOTOX® treatment in deviations over 50 prism diopters, in restrictive strabismus, in Duane's syndrome with lateral rectus weakness, and in secondary strabismus caused by prior surgical over-recession of the antagonist has not been established. BOTOX® is ineffective in chronic paralytic strabismus except when used in conjunction with surgical repair to reduce antagonist contracture.
In addition, BOTOX® Cosmetic, which has distinct labeling, packaging and NDC-coding, has been approved by the FDA for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients ≤65 years of age. BOTOX® Cosmetic is never covered by Medicare.
[2] Soc. Sec. Act §§ 1861(s)(2)(A),(B).

adopted in 1992 and 2001.[3] With the recent FDA approval of botulinum toxin type A for the treatment of patients with severe primary axillary hyperhidrosis, the American Medical Association's CPT Editorial Panel approved 2 new chemodenervation codes, to be implemented January 2006, to report chemodenervation of eccrine glands for the treatment of patients with severe focal hyperhidrosis. These codes are:

64650 Chemodenervation of eccrine glands; both axillae

64653 Chemodenervation of other area(s) (eg, scalp, face, neck), per day

These chemodenervation procedures are similar in many respects to the other well-established chemodenervation procedures requiring specific identification of the sites to be treated, injections into multiple sites by trained practitioners, and monitoring post-injection. The chemodenervation of eccrine gland procedures differ from other chemodenervation procedures in that the Minor's starch iodine test is included as part of the eccrine gland procedure, to identify sites to be treated and to assess effectiveness of previous treatments, whereas in the chemodenervation of muscle procedures, EMG or electrical stimulation or endoscopy may be required as additional procedures to localize the target treatment sites.

We submitted comments in response to the Notice of Proposed Rulemaking supporting a recommendation from the International Hyperhidrosis Society to allow carrier pricing for these new codes in 2006. Although we understand that CMS assigned RVUs for these 2 new codes in agreement with RUC recommendations, we believe the RUC recommendation was premature given last minute revisions to the new codes and descriptors that were made at the time of the RUC meeting last April. We were disappointed that CMS did not adopt the recommendation to allow carrier pricing in 2006.

We believe the RVUs that were assigned for the 2 new codes represent an undervaluation of these chemodenervation procedures.[4] The new chemodenervation of eccrine gland codes are similar to established chemodenervation procedures in terms of physician work and practice expenses. The attached paper published in the Journal of Drugs in Dermatology describes the procedural steps and resources required to perform chemodenervation of the eccrine glands for the treatment of axillary hyperhidrosis.[5] We would urge CMS to give careful consideration to comments received from those who are performing these procedures before finalizing the RVUs for 2007 and beyond.

2. Interim Relative Values for New Code 46505

In addition to the 2 new codes for chemodenervation of eccrine glands, new code 46505 was adopted to report chemodenervation of the internal anal sphincter (e.g., for treatment of anal fissure).[6] We were pleased to see that the valuation for this code appears to reflect the resources required to perform this procedure. We encourage CMS to finalize these RVUs in 2007.

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[3] Code 64612 and 64613 were implemented in 1992 and code 64614 was implemented in 2001.
[4] The relative values are: **64650**: Work 0.70, Practice Expense (non-facility) 0.87, Malpractice Expense 0.06; **64653** Work 0.88, Practice Expense (non-facility) 0.92, Malpractice Expense 0.08.
[5] Glaser DA. Treatment of axillary hyperhidrosis by chemodenervation of sweat glands using botulinum toxin type A. J Drugs Dermatol. 2004;3(6):627-631.
[6] **46505**: Work 2.86, Practice Expense (non-facility) 3.05, Malpractice Expense 0.14

3. Interim Relative Values for New Codes 95873 and 95874

In addition to adopting new codes for chemodenervation procedures, the CPT Editorial Panel created two new codes to report electromyography or electrical stimulation as guidance for chemodenervation procedures. The new codes are:

***95873** Electrical stimulation for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)*

***95874** Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)*

We were disappointed to see that CMS rejected the RUC's recommendations for work relative values for these codes and reduced the RUC's recommendations by 34-percent. The work relative values for these procedures were set at the same level as the limited single needle EMG procedure reported under code 95870.[7] We believe it is appropriate to distinguish between these two procedures because they involve different levels of resources. We would encourage CMS to re-consider the valuation of these procedures and to set at least the needle electromyography procedure (i.e., 95874) at the work relative values recommended by the RUC.

4. Revised Practice Expense Relative Values for 64613 and 64614

In our comment letter responding to the Proposed Rule, we recommended that CMS look carefully at the inputs for codes 64613 and 64614,[8] involving chemodenervation of neck muscles and limb/trunk muscles, respectively, before making any changes to the practice expense relative values for these codes, which we understood were under consideration. We were pleased to see in the Final Rule that the practice expense relative values for these procedures have been maintained.

* * * *

Finally, we would like the thank you for clarifying the provision in the CAP Final Rule that allows for the same application of the drug discard policy under CAP as applies under the current ASP-based payment methodology—i.e., unavoidably unused amounts of drug from an opened, single-use vial will be considered administered and will be eligible for payment under the CAP. Many physicians with whom we work were very concerned about the drug discard issue, and we are very pleased that you have clarified this in the Final Rule.

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[7] **95870**: "Needle electromyography; limited study of muscles in one extremity or non-limb (axial) muscles (unilateral or bilateral), other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters."
[8] **64613**: "Chemodenervation of muscle(s); neck muscle(s) (eg, for spasmodic torticollis, spasmodic dysphonia);" **64614**: "Chemodenervation of muscle(s); extremity(s) and/or trunk muscle(s) (eg, for dystonia, cerebral palsy, multiple sclerosis)."

We appreciate having the opportunity to comment on the Final Rule with Comment Period and hope CMS will consider these recommendations in developing the Proposed Rules for 2007. If you have any questions about our comments, please contact Jim Hayes, Director, Reimbursement Strategy and Healthcare Policy, Neuroscience Division at 714-246-6401 or by e-mail at hayes_jim@allergan.com. Thank you.

Sincerely yours,

/s/ Jim Hayes

Director, Reimbursement Strategy and Healthcare Policy
Neuroscience Division
Allergan Inc.

Attachment—Glaser DA. J Drugs Dermatol. 2004;3(6):627-631.

J Drugs Dermatol 2004 Nov/Dec;3(6):627-31 2004122341

ARTICLES

Treatment of Axillary Hyperhidrosis by Chemodenervation of Sweat Glands Using Botulinum Toxin Type A

Dee Anna Glaser MD

Department of Dermatology, St. Louis University School of Medicine, St. Louis, MO

Abstract

Primary axillary hyperhidrosis is a medical condition characterized by excessive underarm sweating that is thought to result from localized hyperstimulation of sweat glands by cholinergic sympathetic nerve fibers. It can be associated with significant professional, physical, and emotional impairment as well as considerable difficulties in social situations and in personal relationships. Available therapies have been limited by short-lived effectiveness and in some cases significant adverse effects that can put patients at risk for potentially serious complications. Chemodenervation of sweat glands using botulinum toxin type A (BTX-A), which has long-lasting therapeutic efficacy with minimal adverse effects, has emerged as a unique therapy for treating primary axillary hyperhidrosis. This article reviews the chemodenervation procedure, including patient preparation, BTX-A administration, and patient assessment and follow-up.

Introduction

Primary axillary hyperhidrosis is a pathologic condition characterized by excessive underarm sweating. While the exact cause is not known, it is thought to result from hyperstimulation of eccrine glands by the cholinergic sympathetic nerve fibers that innervate them. The etiology of primary hyperhidrosis also appears to have a genetic component, as the frequency of patient-reported family history is consistent with autosomal dominant transmission[1]. The onset of axillary hyperhidrosis is typically in adolescence[2] or young adulthood[3], and its prevalence is highest in the prime working years (ages 18–64 years)[4].

Because of the intensity of its symptoms, primary axillary hyperhidrosis can result in significant impairment in both personal and professional activities and is associated with substantially reduced quality of life[4-7]. Excessive sweating can further result in skin maceration and can be associated with secondary microbial infections in severely affected persons. The emotional disturbance associated with hyperhidrosis may be amplified by the persistence of wetness, staining, and damage to clothing[5]. Consistent with these observations, the quality-of-life burden with primary axillary hyperhidrosis is comparable to or worse than that observed in patients with severe acne, pruritus, or psoriasis[4].

Published data indicate that the prevalence of primary hyperhidrosis is between 0.6% and 2.8%[3,4,10]. Data on the prevalence of hyperhidrosis by focal location and symptom severity are scant. However, a recent study estimated that 0.5% of the US population is afflicted with severe axillary hyperhidrosis, defined as sweating that is barely tolerable or intolerable and that frequently or always interferes with the person's daily activities[3].

Primary axillary hyperhidrosis is treated with a number of therapies, ranging from topical agents to systemic oral medications to surgical sympathectomy. Successful treatment of hyperhidrosis results in substantial improvements in patient functioning and quality of life[11]. However, available treatments have been limited by one or a number of factors, including short-lived effects[12,11] and substantial compensatory sweating[13-15], as well as poor tolerability[16] and potentially serious complications (such as pneumothorax or Horner's syndrome)[13-15,17].

Chemodenervation using botulinum toxin type A (BTX-A) has emerged as a safe and effective treatment for primary axillary hyperhidrosis. This procedure has also been used extensively for the treatment of strabismus, blepharospasm, and head and neck pain associated with cervical dystonia. Botulinum toxin type A acts by blocking neuronal acetylcholine release at the neuromuscular junction and in cholinergic autonomic neurons[18]. When administered at sites of excessive sweating, BTX-A

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produces temporary denervation of the sweat glands, resulting in local reduction in sweating[2].

Randomized controlled studies conducted in Europe and the United Kingdom demonstrate that chemodenervation of sweat glands with BTX-A results in rapid and substantial reductions in axillary sweating, as quantified by gravimetric measurement of sweat production[6,19,20]. These findings have recently been confirmed and extended in a 52-week North American study showing that chemodenervation using BTX-A dramatically reduces axillary sweat production and markedly improves the impairment associated with hyperhidrosis[21]. The primary efficacy end point in this double-blind placebo-controlled trial was the Hyperhidrosis Disease Severity Scale (HDSS), a psychometrically validated single-item 4-point scale in which patients rate how hyperhidrosis interferes with their daily activities and its perceived tolerability[22] (Table 1). Ninety percent of the patients reported that after treatment their hyperhidrosis was tolerable or not noticeable and, at worst, only sometimes interfered with their daily activities. In addition, greater than 80% of patients treated with BTX-A showed a 75% or greater reduction in sweating, measured gravimetrically. The majority of the side effects of BTX-A treatment were mild and transient.

This article reviews the procedures and best clinical practices for treating primary axillary hyperhidrosis by chemodenervation of sweat glands using BTX-A.

Chemodenervation Procedure

Patient preparation

Both axillae are generally treated at the same office visit. There can be considerable variation from patient to patient in the area of excessive sweating within the axillary vault. In some patients, it is confined to the hair-bearing skin and in others it extends beyond this area. In addition, the areas of excessive sweating may vary in the same patient. Because of this inter- and intrapatient variability, mapping the area of excessive sweating is a very important first step in the chemodenervation procedure.

The first step in mapping the hyperhidrotic area is to perform Minor's iodine-starch test, which makes direct visualization of the area possible. Specifically, the axillae are first cleaned and dried thoroughly. The area is then painted with an iodine solution (2 g of iodine in 10 mL of almond oil or castor oil and 90 mL of alcohol). An alternative is to use povidone-iodine with alcohol (eg, Betadine) swabs. After the solution has dried, fine starch powder is evenly dusted over the site. After several minutes, the presence of sweat causes the mixture to turn a dark blue-purple color, making the location of the sweating readily discernible. The hyperhidrotic areas are then outlined with a surgical or dermographic pen and are reprepped with antimicrobial solution.

Reconstitution and dosing of BTX-A

Vacuum-dried purified BTX-A (BOTOX®, Allergan, Irvine, Calif; 100 U per vial) is reconstituted with 4 mL of sterile 0.9% saline solution (25 U/mL). The total injection volume (4 mL) is then drawn into 4 separate 1 mL syringes with a 20- to 22-gauge needle. To minimize patient discomfort, the needle should be replaced with a higher gauge (eg, 30-gauge) needle before injection. On the basis of the results in clinical studies, the recommended dose is 50 U/axilla[6,20,21]. Recent data indicate that there are no significant differences in efficacy or duration

Table 1. Hyperhidrosis Disease Severity Scale (HDSS)

Question: How would you rate the severity of your hyperhidrosis?	Score
My [underarm] sweating is never noticeable and never interferes with my daily activities.	1
My [underarm] sweating is tolerable but sometimes interferes with my daily activities.	2
My [underarm] sweating is barely tolerable and frequently interferes with my daily activities.	3
My [underarm] sweating is intolerable and always interferes with my daily activities.	4

[] indicates alternative wording for axillary patients that can be changed for patients with sweating at other focal locations.

Table 2. Axillary Injection Volume by Number of Injection Sites

Number of injection sites/axilla	Approximate volume (mL)/injection site
10	0.20
12	0.17
14	0.14
16	0.13
18	0.11
20	0.10

of effect between 50-U/axilla and 75-U/axilla doses[21]. Some physicians have suggested that high-dose treatment (200 U/axilla) may be associated with a longer duration of effect[23]; however, this study was preliminary and not well controlled. Since the 50-U/axilla dose is highly effective, well tolerated, and is associated with a durable effect (6 to 7 months)[6,24] clinicians should opt for it in most patients. As shown in Table 2, the injection volume varies according to the number of sites that have been mapped, and 12 to 15 sites is typical in an average patient. Approximately 0.13 mL of BTX-A is given per injection when there are 15 separate injection sites in the hyperhidrotic area of the axilla.

BTX-A administration

Since each treatment site has a ring of effect of approximately 2 cm in diameter, the points of injection should be evenly spaced 1.5 cm apart and be marked before proceeding. To minimize the area of no effect, the sites should be positioned in a staggered manner rather than in a linear fashion (Figure 1). Alternatively, the area can be divided into 1.5-cm squares, with the site of injection in the center of each square[5]. BTX-A is injected slowly and carefully into the intradermal plane of each axilla. The physician should try to obtain a visible wheal that confirms the placement of the drug in the proper plane of the skin. Pressure should then be applied to facilitate hemostasis. After treatment, the hyperhidrotic areas are cleaned and the patient is observed for potential side effects for approximately 20 minutes.

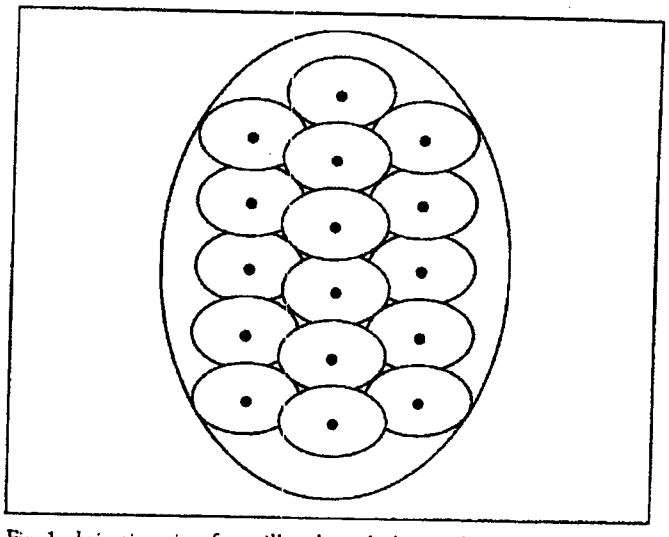

Fig. 1. Injection sites for axillary hyperhidrosis. Botulinum toxin type A diffuses for a fixed distance from the site of injection. To minimize areas of no drug diffusion, the injections should be evenly distributed as shown.

Resources and service time required

A service time of 40 minutes to 1 hour should be reserved for the chemodenervation procedure—10 to 20 minutes for visualizing and mapping the hyperhidrotic areas, 10 to 20 minutes for administering BTX-A, and 20 minutes for monitoring the patient. Table 3 shows the personnel time and medical equipment necessary for the procedure.

Table 3. Approximate Time of Staff and Materials Required in Axillary Chemodenervation

	Patient Preparation	Procedure	Post-Procedure Evaluation	
	Visualizing and mapping the hyperhidrotic area	BTX-A administration	Patient monitoring	Total time
Physician	10–20 min	10–20 min	10 min	30–50 min
Nurse	10 min	10 min	10 min	30 min
Patient	10–20 min	10–20 min	20 min	40–60 min

	Patient Preparation	Procedure
Equipment and Supplies	Starch	0.9% non-preserved saline
	Iodine	5 mL syringe for reconstitution
	Gauze pads	20-G transfer needle
	Shaker	1 mL syringes (4)
	Brush	30-G needles (4)
	Dermographic pen	Gauze pads
	Alcohol pads and towels	

[a] *For all steps: Examination and treatment table, examination paper, and gown.*

Patient assessment and follow-up

A diagnosis of primary axillary hyperhidrosis is indicated when the patient exhibits focal, visible, excessive sweating that has been ongoing for at least 6 months and is characterized by at least two of the following: bilateral and relatively symmetric, impairs daily activities, frequency of at least 1 episode per week, age of onset less than 25 years, positive family history, and cessation during sleep[25]. The HDSS (Table 1) can be used to determine the extent to which hyperhidrosis interferes with daily activities. Treatment with BTX-A is recommended for patients who have failed initial therapy with topical high-strength antiperspirants (ie, aluminum chloride hexahydrate). Clinicians should educate patients on proper use of these agents to maximize tolerability[25].

Determining the severity of hyperhidrosis and assessing the efficacy of treatment over time is key in treating patients with hyperhidrosis. Generally, patients are assessed at the initial office visit and then 7 to 10 days after treatment. Baseline assessments can help to determine hyperhidrosis severity and thus the type of treatment needed. Post-treatment assessments provide information on the efficacy of the treatment and the need for re-treatment. In rare instances patients may show incomplete results by 7 to 10 days after treatment. This generally indicates that some areas of sweating were missed during BTX-A administration or that the injection was placed in the wrong plane of the skin. If this occurs, the axillary vault should be remapped using Minor's iodine-starch test to visualize the hyperhidrotic area and the patient should be re-treated.

Assessment Tools

The HDSS

The HDSS is a validated and reliable single-item 4-point scale for assessing the severity of hyperhidrosis in which patients or physicians rate the patient's tolerability of hyperhidrosis symptoms and the extent to which it interferes with daily activities[22] (Table 1). A score of 3 or 4 (hyperhidrosis is barely tolerable or intolerable and frequently or always interferes with daily activities) indicates hyperhidrosis that requires treatment. The goal of treatment is to move patients to a 1 or 2 on this scale (sweating is tolerable and interferes, at worst, only sometimes with daily activities). Since the HDSS consists of only one question, it can be completed rapidly and easily. As such, it is a practical tool for diagnosing the severity of hyperhidrosis and determining the efficacy of treatment and when re-treatment is needed.

Other assessment tools

The Hyperhidrosis Impact Questionnaire (HHIQ), the Dermatology Life Quality Index (DLQI), and the Illness Intrusiveness Rating Scale (IIRS) are additional validated patient-reported assessments that may be useful in clinical practice and in clinical research with patients with hyperhidrosis. The HHIQ is a comprehensive hyperhidrosis-specific index that evaluates the impairment associated with hyperhidrosis in four domains—occupational, physical, emotional, and social—using a 41-item baseline module and a 10-item follow-up module (completed at various times)[26]. The DLQI is a self-reported questionnaire that is widely used to assess the effect of dermatologic diseases on health-related quality of life[27]. The IIRS is a more general measure of health-related quality of life. However, it has been validated in a population of patients with hyperhidrosis[28].

Gravimetric measurement of sweat production

Gravimetric measurement uses filter paper to quantify the secretion of sweat. With this method, preweighed filter paper is applied to the affected area and the rate of sweat production is calculated as the change in the mass of the filter paper over time (generally 5 minutes). This type of measurement is time intensive and is not routinely or practically performed in clinical practice, being reserved almost exclusively for research purposes. While it appears that this method should provide a quantitative assessment of sweating, it has features that can make it unreliable in clinical practice. First, since there can be considerable intrapatient variability in sweating, this isolated measurement may not accurately reflect the patient's symptoms; sweating can even be totally absent in some patients at some assessment times[4]. In addition, gravimetric measurements may underestimate or overestimate sweating, depending on the surface area covered by the filter paper, and, because there is no established normal range of sweating based on gravimetric assessment, the results can be difficult to interpret.

Summary

Chemodenervation of sweat glands with BTX-A is a valuable treatment option in the dermatologist's treatment armamentarium, as it fills a large unmet need in the treatment of primary focal hyperhidrosis by providing a safe and effective therapy for this often debilitating medical condition. The components of BTX-A treatment include visualizing and mapping the hyperhidrotic area, properly placing the injections, and monitoring the patient. This procedure is a learned skill that will require that the physician be well-versed in cutaneous anatomy and be trained on the proper mapping procedure and injection techniques. This is crucial, as improper mapping and administration can result in a lack of efficacy or an incomplete benefit. After proper training, however, the physician can expect reliable and long-lasting results in patients with primary axillary hyperhidrosis.

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